INTERNATIONAL JOURNAL OF UNANI AND INTEGRATIVE MEDICINE

E-ISSN: 2616-4558
P-ISSN: 2616-454X
https://www.unanijournal.com
IJUIM 2024; 8(1): 34-42
Impact Factor (RJIF): 6.3
Peer Reviewed Journal
Received: 11-01-2024
Accepted: 15-02-2024

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A clinical study of Unani formulation in the management of chronic sinusitis: An open randomized, controlled study

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DOI: https://doi.org/10.33545/2616454X.2024.v8.i1a.259

Abstract
Chronic Sinusitis (*Iltihāb Tajāwīf Al-Anf Muzmin*) is a chronic inflammation of the paranasal sinuses that affects people of all ages. It is usually followed by coryza and cold or sometime resultant of dental infection, deeply seated in upper jaw. The maxillary sinuses are usually involved in the majority of cases. Other sinuses on one or both sides, however, may be affected. It has remained a challenge despite the use of several newer treatment regimens due to relapse, recurrence and resistance. The holistic method of *Unani* treatment can thrive in diseases with temperamental association and evidences of *Unani* medicine effectiveness in *Iltihāb Tajāwīf Al-Anf Muzmin* (Chronic Sinusitis) have been found throughout history, but it lacks the scientific data for validation. As a result, a Unani formulation was chosen for the clinical trial in *Nazla Bārid Muzmin* to assess safety and efficacy on scientific parameters. The objective of this study was to evaluate Safety and efficacy of Unani formulation (*Joshānda*), to Study various aspects of chronic sinusitis with reference to classical as well as modern literature and to compare the effects of Unani formulation with the known standard control in the management of chronic sinusitis.
Methods: In an open labelled, randomized and standard controlled trial, the Unani formulation (*Joshānda*) was given to the test group in a dose of 100ml once a day before breakfast orally and *"Nuskha Joshanda Nazla Barid"* (standard control) was given after ethical approval. Both the drugs were continued for a period of 45 days in each group. After which all the patients were assessed for subjective and objective parameters. The results were analyzed statistically.
Results: A significant improvement (p<0.001) was observed in subjective parameters and objective parameters.
Conclusion: The Unani polyherbal formulation of test drug was effective in improving the subjective and objective parameters as compared to control drug. Both the treatment were generally well tolerated.

Keywords: *Iltihāb tajāwīf al-anf muzmin*, *nazla bārid muzmin, unani* formulation, decoction, chronic sinusitis

Introduction
According to *Ghulam Jeelan*i, the word *"Nazla"* is derived from the Arabic word *"Nuzool"*, which means "dripping down", and is known in Persian as *"Rezish"*. He explained that *Nazla* is a condition in which the nasal passages are irritated and nasal secretion drips down into the chest, thoracic area, or larynx [1].
In *Unani* literature, '*Nazla Barid'* has been described as a disease in detail with signs and symptoms along with treatment under the chapter of '*Nazla wa Zukām'*. According to Unani physicians, *Nazla* (catarrh) is a condition in which the phle gm or the morbid material dripping down towards the throat, if the same flow towards the nose is called as *Zukām* (coryza) [1].
There are some principles for disease nomenclature in the *Unani* System of Medicine. The disease is referred to as "*Waram*" rather than "*Iltihāb*". As a result, *Iltihāb*, which means "burning and flame", has been identified as a symptom of *Nazla Hārr*. As a result, sinusitis is better defined as *Iltihāb Tajāwīf al-Anf* [2].
Various Unani physicians have described *Nazla* in lieu of the signs and symptoms of *Warm Tajaweef-i-Anaf* (sinusitis), with its type's *Ḥād* and *Muzmin*. And *Ibn Sina* broadly described the etiopathogenesis, types, clinical presentation and treatment of *Nazla wa Zukām* in his book *"Al-Qānūn Fi'l Ṭibb"* [3].

Ibne Sina describes the main causative factors for development of *Nazla wa Zukām* as *Asbab-i-Kharjia* (extrinsic factors). Extrinsic factors are excessive cold & dry condition, excessive hot & wet conditions, excessive hot & dry condition and some other factors are dust, feather, pollen, cotton etc. They may alter in temperament of nasal cavity & may produce *Nazla wa Zukām* [3].

Mohammed Tabri divides *Zukām* into three categories and then discussed the causes of each type. For example, the first type is caused by environmental factors such as prolonged exposure to cold air and other cold-related conditions. The second form is caused by excessive hotness in the head, which can lead to the accretion of morbid matter in the brain. Excessive sleep in the sun light, prolonged exposure to sunshine, and application of warm hair oil are some of the factors. The accumulation of humours in the body, mainly in the brain, results in the third type [4]. Sinusitis is the acute and chronic inflammation of the paranasal sinuses. It is also called as rhinosinusitis. Inflammation may be localized to a single sinus or it may be multi-sinusitis or Pansinusitis and it can be unilateral or bilateral. Most commonly involved sinus is Maxillary sinus. The ethmoidal, frontal and sphenoid sinuses are less commonly involved. Rhinosinusitis is a common chronic disease that affects people of all ages around the world [5-8].

Chronic sinusitis is a chronic inflammation of the sinus or nasal passage occurring for more than 12 weeks at a time or chronic rhinosinusitis is characterized as more than 12 weeks of symptoms devoid of full resolution, and it can be divided into chronic sinusitis with nasal polyp and chronic sinusitis without nasal polyp [9-11].

The prevalence of chronic sinusitis found to be approx. 5-15% of the general populations. According to epidemiology some correlation found between the chronic sinusitis and active cigarette smoking, perennial allergic rhinitis, air pollution [12, 13].

Chronic sinusitis is caused by a number of factors. It is described as acute sinusitis that has not reacted to treatment and has resulted in permanent changes and edema of the sinus mucosa. This may lead to secondary obstruction of the sinus ostia, which prevents aeration and drainage and thus promotes infection [14].

Most Common clinical feature of Chronic Sinusitis (CS) is purulent nasal discharge, it also includes nasal obstruction, nasal discharge, halitosis (bad breath), headache. Symptoms may variable and it may be localized to the nose, ear & throat or maybe generalized [5, 7, 8].

Since no medication in conventional system of medicine can completely cure chronic sinusitis, the main goal of treatment is to manage symptoms and prevent complications. They use decongestants, antihistaminic, antibiotics, and surgical procedures such as Antral puncture and drainage in the modern setting. Sinusitis patients are reliant on analgesics, which have many side effects and cannot be used for long periods of time. Some complication occur due to antibiotics are pansinusitis, pharyngitis, laryngitis, middle ear infection etc [15]. 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) [16].

The Unani system provides both local and general care. The viscid humours that are clogged in the sinuses are liquified by regular inhalations as a local remedy. To fascilitate the elimination of the *Ma'adda* must be liquefied (*Nuzj wa Tanqiya*). Moderating the altered humours and fixing the altered temperament are the main treatment modalities [17].

Materials and Methods

The study entitled "A clinical study of the effects of *Unani* formulation (*Joshānda*) with reference to the Standard control in the management of *Iltihāb Tajāwīf Al-Anf Muzmin* (Chronic Sinusitis)" was conducted at Regional Research Institute of Unani Medicine, Naseem Bagh, Srinagar J&K. An inclusive protocol was framed and approval was obtained from the Institutional Ethics Committee of Regional Research Institute of Unani Medicine (RRIUM), Srinagar. IEC number RRIUM/KU/ 2018-19/Tech/IEC/ dated 29.03.2019 and having CTRI (Clinical Trials Registry-India) number CTRI/2020/05 /025388 dated 27.05.2020. Recruitment of the patients was done during the study duration of 12 months, from OPD/IPD of RRIUM Hospital, on the basis of detailed history, physical examination and investigation. After taking voluntary written consent from each eligible patient, they were randomly distributed by randomization charted by the computer-generated method in two groups, test group and control group. The blue print of the study was conceptualized as material and methods which can be described under few headings for expedient comprehension. The patient's summary is given in Figure 3.

1. Criteria for selection of Subjects

a. Inclusion criteria

1. Clinically diagnosed patients of chronic sinusitis of more than 12 weeks duration.
2. Patients Irrespective of gender.
3. Patients in the age group of 20-60 years.
4. SNOT 22 more than 7.
5. Patients who have agreed to sign the informed consent form and follow up the protocol.

b. Exclusion criteria

1. Patients below the age of 20 and above the age of 60 years.
2. Patients with Atrophic rhinitis.
3. Patients with Deviated Nasal Septum.
4. Patients with Nasal polyps / Nasal growth / Adenoids.
5. Patients with systemic diseases like, Diabetes, cardiovascular disease, impaired renal and hepatic functions, HIV, T.B and COPD.
6. Patients who refuse to give the written consent for the study.
7. Pregnancy and lactating women.
8. Any of them not covered under inclusive criteria.

2. Selection of Subjects

After the screening of the patients, the selected cases of *Iltihāb Tajāwīf al-Anf Muzmin* (Chronic sinusitis) with complete history includes clinical symptoms with duration, present history, past history, personal history, family history, socioeconomic status on the basis of Kuppuswamy Socioeconomic Scale, general physical examination and systemic examination was carried out and recorded on a prescribed case record form (CRF) which was designed according to the objectives of the study. Vitals were checked, pulse rate, blood pressure, respiratory rate and temperature in Fahrenheit. Any other relevant finding during general physical examination was recorded in CRF.

Detailed systemic examination of nervous system, respiratory system, cardiovascular system and digestive system was done carefully to look for any finding of other serious illness and recorded in CRF.

3. Assessment of *Mizāj* (temperament)
During the clinical examination, each patient's *Mizāj* was evaluated using the *Ajnās-i-Ashra* (10 different parameters) described in *Unani* literature.

4. Informed consent
Patients fulfilling the inclusion criteria were provided the information sheet having details regarding nature of the study, the intervention to be used, method of treatment, information about the trial drug, drug dose, route of administration, protocol and duration of study etc. Every patient was given enough time to read the contents of the information sheet, in addition to verbally reminding them of the same. They were given the opportunity to ask some direct questions about the study. They were asked to sign the consent form after they were satisfied and decided to participate in the study.

5. Investigations
Investigations were carried out before and after treatment in every case enrolled in OPD/IPD i.e. 0th day and 46th day.

Hb%	Serum creatinine
TLC	Blood urea
DLC	Serum bilirubin
ESR	Serum alkaline phosphates
RBS (Random blood sugar)	SGOT
AEC (Absolute Eosinophils count)	SGPT
Urine (routine & microscopic)	X-ray PNS (Water's view)

6. Method of collection of data
A. Subjective parameters
1. Nasal obstruction
2. Purulent nasal discharge
3. Constant sinus pressure
4. Chronic cough
5. Halitosis
6. Hyposmia

B. Objective parameters
1. X-ray PNS (water's view).
2. SNOT-22.
3. AEC

7. Study design: The Study was designed as a randomized, open labelled controlled study.

8. Sample size: Total numbers of patients to be selected were 40 divided into two groups;
Group A (Test group): 20 patients.
Group B (Control group): 20 patients.

9. Allocation of subjects into groups
The patients were randomly allocated by using computer random sequence generator chart into two groups, each having 20 patients i.e. 20 in test group (Group A) and 20 in standard control group (Group B).

10. Duration of study: One year.

11. Duration of Protocol
Trial duration for both the test and control group was ascertained as 45 days.

12. Follow up during treatment: Every 15 days i.e. on 15, 30 & 45 days of study.
Patients were kept under observation from day first and were advised to repeat after every 15 days. After every visit patient were acquired about the progression and regression of their symptoms and were also subjected to examination to assess the clinical findings & recorded in CRF. Treatment in both groups was started from day 1st after accessing the investigation reports, up to 45thday. Reinvestigations were done on 46th day.

13. Test drug formulation
This herbal formulation known as *Joshānda* (decoction) was selected from the *Ikseer-i-Āzam* (Urdu Translation) [18].
The Ingredients of *Nuskha (Unani formulation)* along with their doses are given below;

Drug Name	Botanical Name	Dosage
Asl-us-soos	*Glycyrrhiza glabra* Linn	4.5 gm
Badiyan	*Foeniculum vulgare* Mill	4. 5 gm
Banafsha	*Viola odorata*	4.5 gm
Gaozaban	*Borago officinalis* Linn	4.5 gm
Hansraj	*Adiantum capillus veneris*	4.5 gm
Maveez munaqqa	*Vitis vinifera* Linn	15 in number
Sapistan	*Cordia dichotoma*	15 in number
Misri	*Crystallised sugar*	18 gm

13.1 Method of Preparation of Test drug
The test and Control drugs were purchased by the purchasing committee of the Regional Research Institute of Unani Medicine from the local market. The drugs were authenticated by centre for biodiversity and taxonomy, University of Kashmir. The voucher specimen number is KASH/Voch/speci/CBT and was submitted in the above said department. *Asl-us-soos* (4.5 gm), *Badiyan* (4.5 gm), *Banafsha* (4.5 gm), *Gaozaban* (4.5 gm), *Hansraj* (4.5 gm), *Sapistan* (15 in number), *Maveez munaqqa* (15 in number), *Misri* (18 gm) each, these drugs were soaked in 400 ml of water for whole night and next morning it was boiled till the quantity of water was reduced to 100 ml (one fourth). The decoction (*Joshānda*) was filtered and *Misri* (18 gm) was dissolved in it.

Fig 1: Showing *Joshānda* (Decoction) of test drugs

13.2 Dose and duration: 100 ml once a day early in the morning.

13.3 Route of administration: Oral route.

14. Standard control: *Nuskha Joshānda Nazla Barid* [19].
The constituents of *Nuskha Joshānda Nazla Barid* (*Unani* formulation) along with their doses are given below;

Drug Name	Botanical Name	Dosage
Gul-i-Banafsha	*Viola odarata linn*	7 gm
Tukhm-i-Khatmi	*Althea officinalis linn*	7 gm
Tukhm-i-khubazi	*Malva sylvestris linn*	7 gm
Barg-i-Gaozaban	*Borago officinalis linn*	5 gm
Unnab	*Zizyphus vulgaris lau*	5 in numbers
Misri	*Crystallised sugar*	20 gm

14.1 Method of preparation and dosage
These drugs were soaked in 400 ml of water for entire night. Next morning-soaked drugs along with same water were allowed to boil till water reduces to half. The obtained filter was divided into two halves and each half advised to be taken orally in the morning and evening separately before meals. The formulation selected for standard control is of proven efficacy.

14.2 Dosage and duration: 100 ml twice a day.

Fig 2: Showing *Joshānda* (Decoction) of Control drugs

14.3 Route of administration: Oral route.

15. Efficacy assessment
The assessment of the efficacy of test and control drugs was done on the basis of two types of parameters.
a. Subjective parameters
b. Objective parameters
Subjective parameters are those of Visual Analogue Scale (VAS) [16, 20] score and objective parameters include AEC, SNOT-22 Questionnaire score [20] and X-ray PNS (water's view) [19]. Since the parameters differ from patient to patient, grading of subjective parameters according to VAS score helps for the appropriate assessment and statistical evaluation appraise the efficacy of test drug and control drug.
Grading of subjective parameters and objective parameters i.e. SNOT-22 and the score was noted in the case report form (CRF) before starting the treatment and at every follow up till the end of the treatment. While grading of other objective parameters i.e. X-ray PNS were done and recorded only before starting and after accomplishment of the treatment.

16. Subjective parameters
16.1 Grading of Nasal obstruction
0-3=Mild cases
4-7=Moderate cases
8-10=Severe cases

16. 2 Grading of Purulent nasal discharge
0-3=Mild cases
4-7=Moderate cases
8-10=Severe cases

16. 3 Grading of Constant sinus pressure
0-3=Mild cases
4-7=Moderate cases
8-10=Severe cases

16. 4 Grading of Chronic cough
0-3=Mild cases
4-7=Moderate cases
8-10=Severe cases

16. 5 Grading of Halitosis
0-3=Mild cases
4-7=Moderate cases
8-10=Severe cases

16. 6 Grading of Hyposmia
0-3=Mild cases
4-7=Moderate cases
8-10=Severe cases

17. Objective parameters
17.1 Assessment of X-ray PNS (Opacity)
It is graded as;

Grading	Opacity
Grade 0	No opacity
Grade 1	Mild opacity
Grade 2	Moderate opacity
Grade 3	Severe opacity

17.2 Assessment of X-ray PNS (Mucosal Thickening)
It is graded as;

Grading	Mucosal Thickening
Grade 0	No Mucosal thickening
Grade 1	Mild Mucosal thickening
Grade 2	Moderate Mucosal thickening
Grade 3	Severe Mucosal thickening

18. Withdrawal criteria
- Patients who fail to follow the protocol.
- Any adverse reaction or adverse event.
- Drug defaulter

19. Method applied
In doing the study GCP (Good Clinical Practice) was adhered throughout and regular monitoring of each case was performed as stated above.

20. Statistical Analysis

For statistical analysis, recorded data was compiled and entered in a spread sheet and then exported to data editor of SPSS version 20.0 and Graph pad prism software. The continuous variables were expressed as Mean ± Standard deviation and categorical variables were expressed in terms of frequency and percentage. Chi-square test was employed for inter group comparison of categorical variables and for intra group analysis of categorical variable with more than two levels we applied McNemar-Bowker's test. Student's independent t-test was employed for inter-group analysis of data and for intra-group analysis paired t-test was applied subject to the condition that data is measured on continuous scale and satisfies assumption of normality. The graphical representation of data was presented by means of 2D and 3D bar graphs. A p-value of less than 0.05 was considered statistically significant.

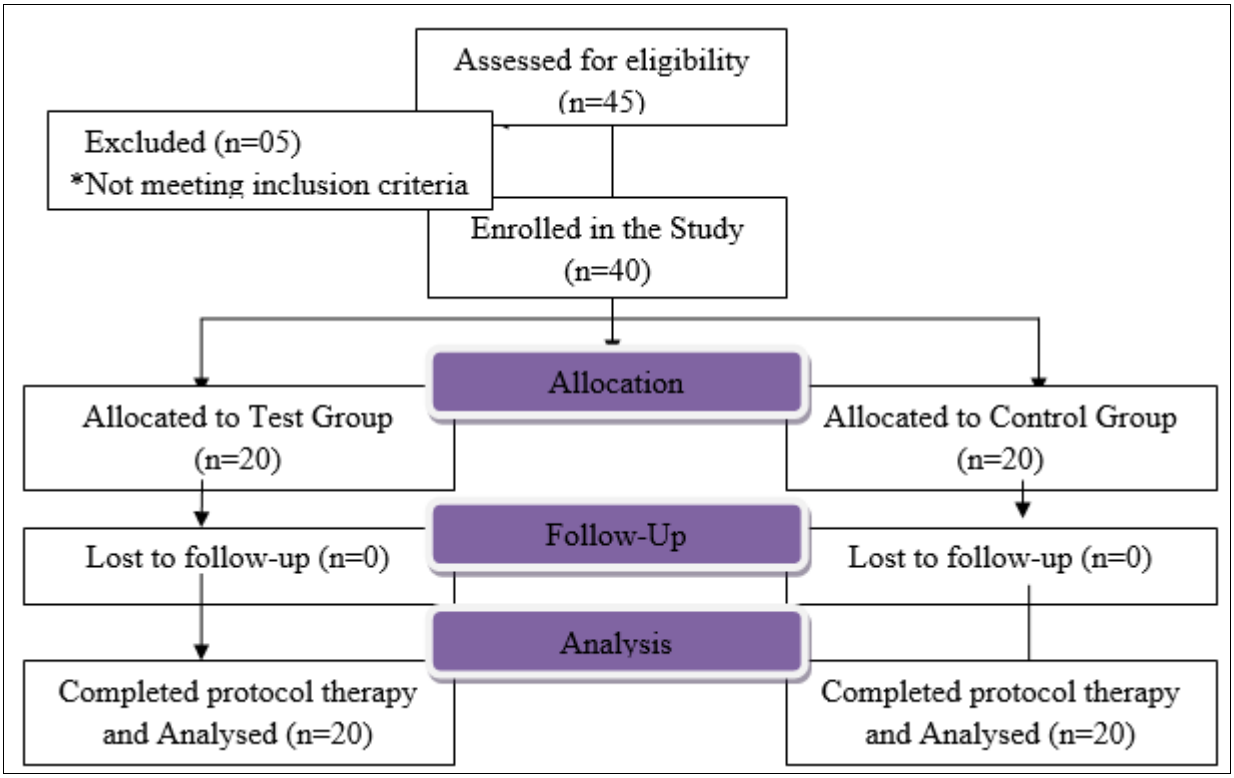

Fig 3: Patients Summary (Consort flow diagram)

Observations and Results

Table 1: Showing demographic characteristics of the participants

Baseline Characteristics	Study Groups		
	Test group (n=20), n(%)	Control group (n=20), n (%)	Total (n=40), n (%)
Males	11 (55%)	11 (55%)	22 (55%)
Females	09 (45%)	09 (45%)	18 (45%)
Average age (±S.D) years	33.88(±10.01)	34.75(±9.32)	33.88(±10.01)
20-30 years	09 (45%)	08 (40%)	17 (43%)
30-40 years	05 (25%)	05 (25%)	10 (25%)
40-50 years	04 (20%)	05 (25%)	09 (23%)
50-60 years	02 (10%)	02 (10%)	04 (10%)
Damwī Mizāj	06 (30%)	01 (05%)	07 (18%)
Balghamī Mizāj,	14 (70%)	19 (95%)	33 (83%)

Table 1, In this present study we enrolled 40 patients, it was found that 55% were males and 45% were females in each group. The 43% patients were found between 20-30 years of age, 25% were 30-40 years of age, 23% were 40-50 years of age and 10% were 50-60 years of age. The average age (±SD) were 33.88 (±10.01) years and 34.75 (±9.32) years in the test and control group respectively, suggesting that all the age groups are usually involved with high incidence in the age group of 20-30 years. Overall 83% patients were found of *Balghamī Mizāj*, followed by 18% patients were found of *Damwī Mizāj.* None of the patients among study groups were having *Safrāwī Mizāj* and *Sawdāwi Mizāj*.

Table 2: Showing distribution of Participant according to their Symptoms

			Nasal obstruction	Purulent Nasal Discharge	Constant Sinus pressure	Chronic cough	Halitosis	Hyposmia
Test group (n=20), n(%)	BT	Mild	03 (15%)	15 (75%)	07 (35%)	13 (65%)	19 (95%)	20 (100%)
		Moderate	11 (55%)	05 (25%)	12 (60%)	07 (35%)	01 (05%)	00 (0%)

		Severe	06 (30%)	00 (0%)	01 (05%)	00 (0%)	00 (0%)	00 (0%)
	AT	Mild	20 (100%)	20 (100%)	20 (100%)	20 (100%)	20(100%)	20 (100%)
		Moderate	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)
		Severe	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)
Overall percent improvement			85%	25%	65%	35%	05%	0%
P-value			<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*
Control group (n=20), N(%)	BT	Mild	05 (25%)	12 (60%)	08 (40%)	08 (40%)	20(100%)	20 (100%)
		Moderate	09 (45%)	07 (35%)	12 (60%)	12 (60%)	00 (0%)	00 (0%)
		Severe	06 (30%)	01 (05%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)
	AT	Mild	20 (100%)	20 (100%)	20 (100%)	20 (100%)	20(100%)	20 (100%)
		Moderate	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)
		Severe	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)	00 (0%)
Overall percent improvement			75%	40%	60%	60%	0%	0%
P-value			<0.001*	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

Table No: 02, We observe that, the difference in Subjective parameters at post treatment comparing to the baseline of the symptoms Nasal obstruction, Constant Sinus pressure, Halitosis, had been found clinically and statistically significant in test group with p-value <0.001. The overall percentage improvement in patients with respect to Nasal obstruction is 85%, Constant Sinus pressure is 65% and Halitosis 05% is more than what we observed in control group Nasal obstruction (75%), Constant Sinus pressure (60%) and Halitosis (0%). Hence the test drug was found more effective in resolving these symptoms.

Table 3: Showing X-ray PNS Opacity before and after the treatment in both the groups

	Test Group (n=20), n (%)				Control Group (n=20), n (%)			
	BT	**AT**	**Overall % improvement**	**p-value**	**BT**	**AT**	**Overall % improvement**	**P-Value**
No opacity	07 35%)	15(75%)	50	<0.001*	07 (35%)	12 (60%)	45	<0.001*
Mild	01(05%)	03(15%)			01 (05%)	05 (25%)		
Moderate	09(45%)	02(10%)			08 (40%)	03 (15%)		
Severe	03(15%)	00(0%)			04 (20%)	00 (0%)		

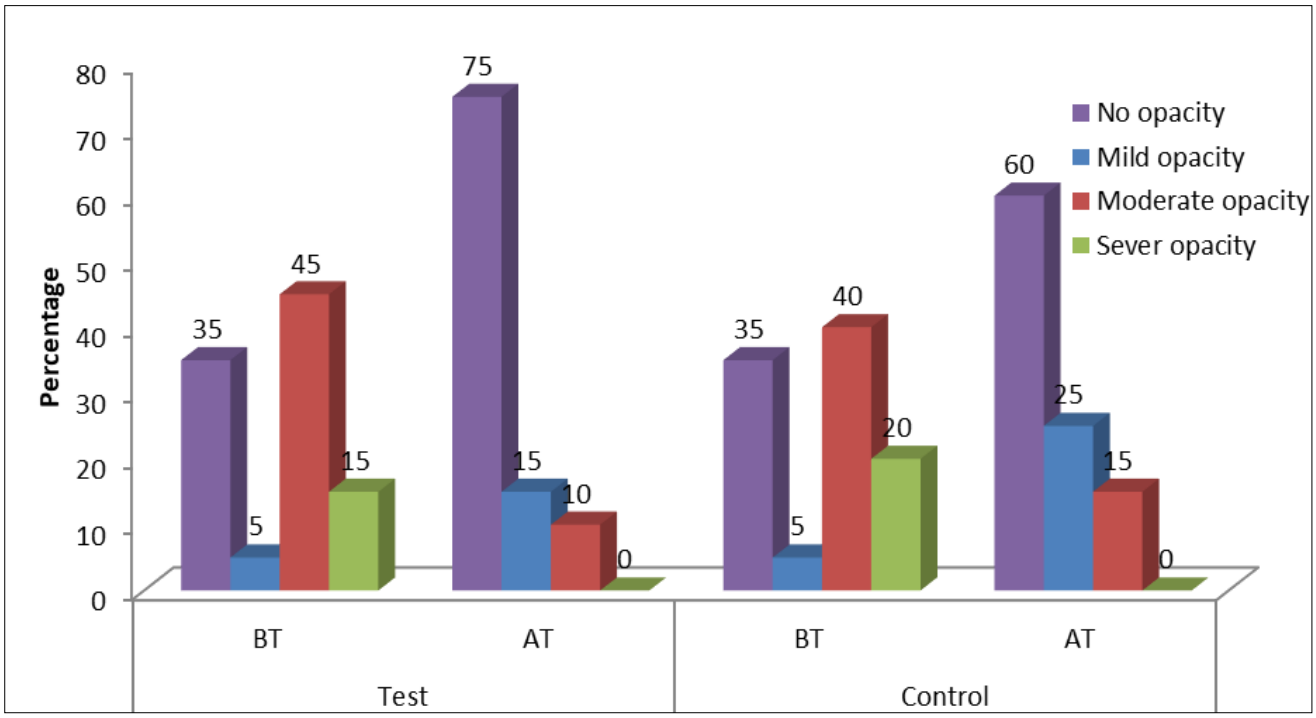

Fig 4: Showing X-ray PNS-Opacity before and after the treatment in Test and Control group

Table 3 and Figure 4: In Test group before treatment, 7 (35%) patients revealed no opacity, 9 (45%) revealed moderate opacity, 3 (15%) revealed severe opacity and one (5%) revealed mild opacity in X-ray PNS and after treatment 15 (75%) patients revealed no opacity, three (15%) revealed mild opacity and two (10%) revealed moderate opacity in X-ray PNS. The overall improvement is 50 percent. This data was found statistically highly significant with p value < 0.001*. In Control group before treatment, 7 (35%) patients revealed no opacity, 8 (40%) revealed moderate opacity, 4 (20%) revealed severe opacity and one (5%) revealed mild opacity in X-ray PNS and after treatment 12 (60%) patients revealed no opacity, 5 (25%) revealed mild opacity and 3 (15%) revealed moderate opacity in X-ray PNS. The overall improvement is 45 percent. This data was found statistically highly significant with p value < 0.001*. The test drug was found more effective in resolving the X-ray PNS-Opacity.

Table 4: Showing X-ray PNS Mucosal Thickening before and after the treatment in both the groups

	Test Group (n=20), n (%)				Control Group (n=20), n (%)			
	BT	**AT**	**Overall % improvement**	**P-Value**	**BT**	**AT**	**Overall % improvement**	**P-Value**
No M. Thickening	08 (40%)	13 (65%)	35	0.049*	13 (65%)	13 (65%)	15	0.0612*
Mild	04 (20%)	06 (30%)			01 (05%)	04 (20%)		
Moderate	07 (35%)	01 (05%)			04 (20%)	03 (15%)		
Severe	01 (05%)	00 (0%)			02 (10%)	00 (0%)		

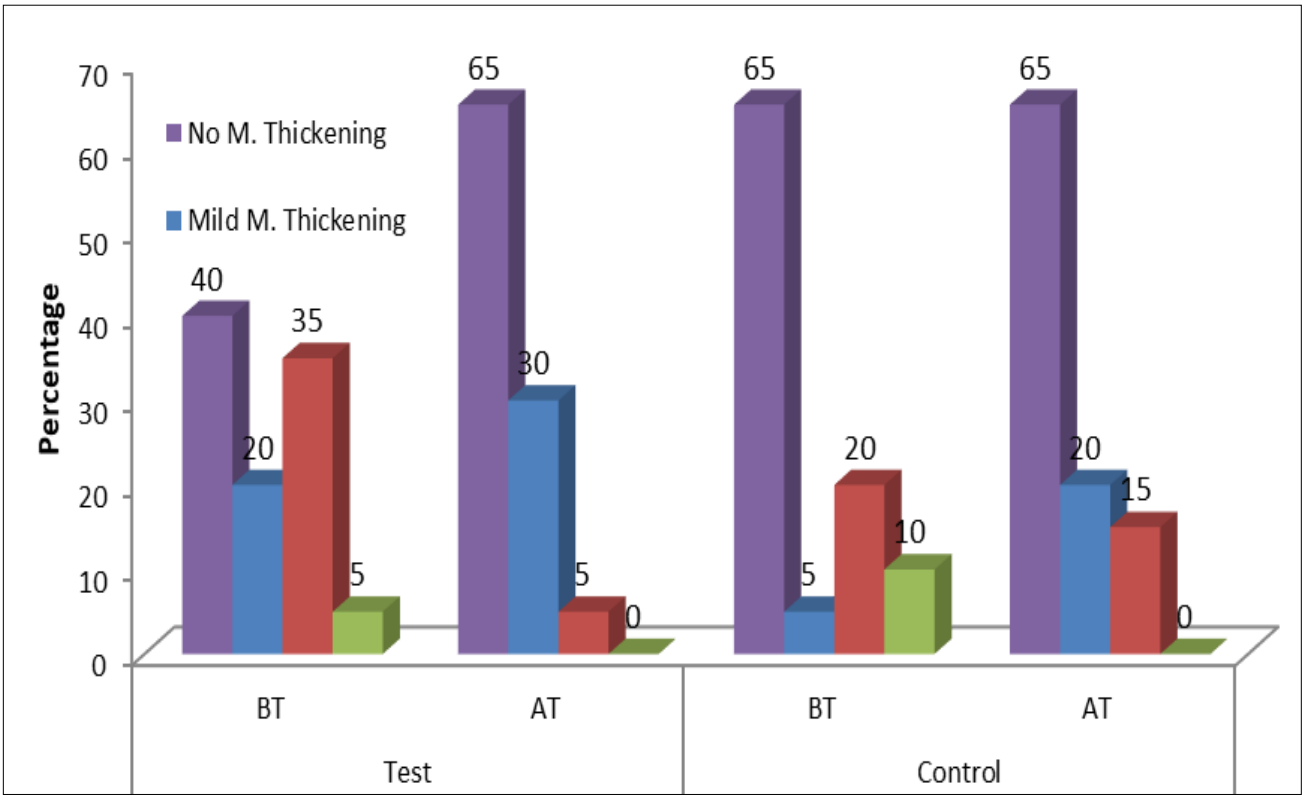

Fig 5: Showing X-ray PNS-mucosal thickening before and after the treatment in test and control group

Table 4 and Figure 5: In Test group, before treatment out of 20 patients, 8 (40%) patients revealed no mucosal thickening, 7 (35%) revealed moderate mucosal thickening, 4 (20%) revealed mild mucosal thickening and one (5%) revealed severe mucosal thickening in X-ray PNS and after treatment 13 (65%) patients revealed no mucosal thickening, 6 (30%) revealed mild mucosal thickening and one (5%) revealed moderate mucosal thickening in X-ray PNS. The overall improvement is 35 percent. This data was found statistically significant with p value < 0.049*.

In Control group, before treatment out of 20 patients, 13 (65%) patients revealed no mucosal thickening, 4 (20%) revealed moderate mucosal thickening, two (10%) revealed severe mucosal thickening and 1 (5%) revealed mild mucosal thickening in X-ray PNS and after treatment 13 (65%) patients revealed no mucosal thickening, 4 (20%) revealed mild mucosal thickening and three (15%) revealed moderate mucosal thickening in X-ray PNS. The overall improvement is 15 percent. This data was found statistically significant with p value <0.0612*. The test drug was found more effective in resolving the X-ray PNS- Mucosal Thickening.

Table 5 and Figure 6: It shows that there is a significant difference (p-value<0.001*) in SNOT score before and after the treatment in test as well as control group. We observe that there were 12 moderate and one severe case in test group, while 11 moderate cases in control group before the treatment which improved to mild status after the treatment. The overall percentage improvement in patients with respect to SNOT score in test group is 65% which is more than what we observed in control group i.e. 55%.

Table 5: Showing SNOT 22 Score before and after the treatment in both the groups

	Test Group (n=20), n (%)				Control Group (n=20), n (%)			
	BT	**AT**	**Overall % improvement**	**P-Value**	**BT**	**AT**	**Overall % improvement**	**P-Value**
Mild	07 (35%)	20(100%)	65	<0.001*	09(45%)	20(100%)	55	<0.001*
Moderate	12 (60%)	00 (0%)			11(55%)	00(0%)		
Severe	01 (05%)	00 (0%)			00 (0%)	00(0%)		

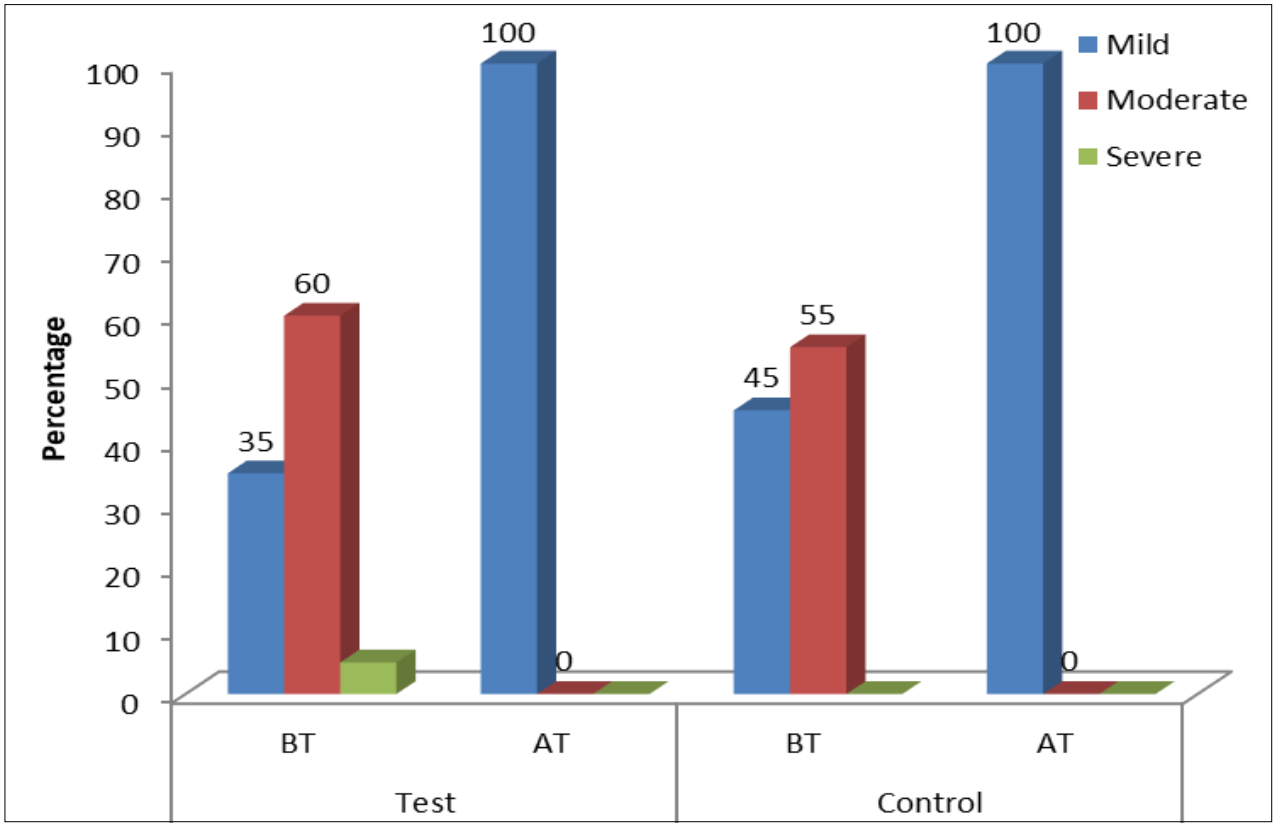

Fig 6: Showing SNOT-Score before and after the treatment in Test and Control group

Discussion

After completion of the trial the score of both subjective and objective parameters obtained post treatment was compared. For statistical analysis, recorded data was compiled and entered in a spread sheet and then exported to data editor of SPSS version 20.0 and Graph pad prism software. It is evident that all the age groups are usually involved with high incidence in the age group of 20-30 years [8].

In present study out of 40 patients, 33 (83%) patients were found of *Balghamī al-Mizāj*, followed by 07 (18%) patients were found of *Damwī al-Mizāj.* None of the patients among study groups were having *Safrāwīal-Mizāj* and *Sawdāwi al-Mizāj* as assessed by temperament scale. According to the Unani system of medicine, the majority of *Nazla Barid* patients have *Barid Mizāj* [3, 18, 21]. Patients with *Balghamī Mizāj (Barid mizaj)* had a higher incidence, which is consistent with a study conducted by Dar KA *et al.* [22].

From Table no 2, it is evident that, the difference in Subjective parameters at post treatment comparing to the baseline of the symptoms Nasal obstruction, Constant Sinus pressure, Halitosis, had been found clinically and statistically significant in test group with p-value <0.001. The overall percentage improvement in patients with respect to Nasal obstruction is 85%, Constant Sinus pressure is 65% and Halitosis 05% is more than what we observed in control group Nasal obstruction (75%), Constant Sinus pressure (60%) and Halitosis (0%). Hence the test drug was found more effective in resolving these symptoms.

Table 3: In Test group before treatment, 7 (35%) patients revealed no opacity, 9 (45%) revealed moderate opacity, 3 (15%) revealed severe opacity and one (5%) revealed mild opacity in X-ray PNS and after treatment 15 (75%) patients revealed no opacity, three (15%) revealed mild opacity and two (10%) revealed moderate opacity in X-ray PNS.

In Control group before treatment, 7 (35%) patients revealed no opacity, 8 (40%) revealed moderate opacity, 4 (20%) revealed severe opacity and one (5%) revealed mild opacity in X-ray PNS and after treatment 12 (60%) patients revealed no opacity, 5 (25%) revealed mild opacity and 3 (15%) revealed moderate opacity in X-ray PNS. The overall improvement is 50 percent in test group which is more as compared to control group i.e. 45 percent. Hence the test drug was found more effective in resolving the X-ray PNS-Opacity.

Table 4: In Test group, before treatment out of 20 patients, 8 (40%) patients revealed no mucosal thickening, 7 (35%) revealed moderate mucosal thickening, 4 (20%) revealed mild mucosal thickening and one (5%) revealed severe mucosal thickening in X-ray PNS and after treatment 13 (65%) patients revealed no mucosal thickening, 6 (30%) revealed mild mucosal thickening and one (5%) revealed moderate mucosal thickening in X-ray PNS.

In Control group, 13 (65%) patients revealed no mucosal thickening, 4 (20%) revealed moderate mucosal thickening, two (10%) revealed severe mucosal thickening and 1 (5%) revealed mild mucosal thickening in X-ray PNS and after treatment 13 (65%) patients revealed no mucosal thickening, 4 (20%) revealed mild mucosal thickening and three (15%) revealed moderate mucosal thickening in X-ray PNS. The overall improvement is 35 percent in control group which is much more than the control group i.e. 15 percent. Hence the test drug was found more effective in resolving the X-ray PNS- Mucosal Thickening.

Table 5 shows that there is a significant difference (p-value < 0.001*) in SNOT score before and after the treatment in test as well as control group. We observe that there were 12 moderate and one severe case in test group, while 11 moderate cases in control group before the treatment which improved to mild status after the treatment. The overall percentage improvement in patients with respect to SNOT

score in test group is 65% which is more than what we observed in control group i.e 55%. Hence the test drug was found more effective in reducing the SNOT 22 Score.

Conclusion

The present study illustrated that test as well as control drug formulations were found effective in marked improvement in clinical features of patients suffering from chronic sinusitis. It was also observed that the effect of test drug in some parameters like nasal obstruction, sinus pressure, X-ray PNS-Opacity was statistically highly significant and encouraging in comparison with control drug. However, in some parameters like nasal discharge and chronic cough, control drug was statistically very significant and encouraging in comparison with test drug. No significant change was seen in the mean value of AEC before and after the treatment in both groups. However, long term study on larger sample size is required for further exploration of the effects of test drug and to determine their mechanism of action with modified methodology.

Acknowledgement

This work was accomplished with special regards to Dr. Seema Akbar (Assistant Director I/c) for her kind cooperation, encouragement and patronage and whole team of Regional Research Institute of Unani Medicine.

Declarations

Funding: The study was funded by the Central Council for Research in Unani Medicine (CCRUM), an autonomous organization under the Ministry of AYUSH, Government of India.

Conflict of Interest: Authors declared that there was no conflict of interest.

Ethical approval: The study was approved by Ethical Committee

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How to Cite This Article
Alam MT, Ahmed MSM, Rather SA, Khan N, Kalam MA. A clinical study of Unani formulation in the management of chronic sinusitis: An open randomized, controlled study. International Journal of Unani and Integrative Medicine. 2024;8(1):34-42.