


Human Journals

Research Article

July 2023 Vol.:25, Issue:1

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To Evaluate the Efficacy of *Safoof-E-Banafsha* in *IttiHab-E-Tajaweef-E-Anaf Muzmin* (Chronic Sinusitis): An Open Observational Study



IJSRM

INTERNATIONAL JOURNAL OF SCIENCE AND RESEARCH METHODOLOGY

An Official Publication of Human Journals



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Submitted: 17 June 2023

Accepted: 15 July 2023

Published: 30 July 2023

Keywords: *IttiHab-e-Tajaweef-e-Anaf Muzmin*, Chronic Sinusitis, *Safoof-e-Banafsha*, Headache, Nasal Discharge.

ABSTRACT

Aim: To evaluate the efficacy of *Safoof-e-Banafsha* in the management of *IttiHab-e-Tajaweef-e Anaf Muzmin* (Chronic Sinusitis).

Material and Methods: An open observational clinical study was carried out in the of Dept. of Moalajat, Z.V.M. Unani Medical College & Hospital, Pune. Sixty diagnosed patients were included in the study after obtaining the consent form. *Safoof* prepared from *Gul-e-Banafsha* was given 5 grams orally twice daily for 21 days. Follow up was done every 7th day for 4 weeks. The subjective criteria were headache, nasal discharge, nasal obstruction, sneezing and tenderness. The objective parameter was X-ray PNS (water's view). The result was analyzed by applying paired 't' test.

Result: The study showed significant improvement in the signs and symptoms of *IttiHab-e-Tajaweef-e Anaf Muzmin* (Chronic Sinusitis).

Conclusion: *Safoof-e-Banafsha* is effective in *IttiHab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis)



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INTRODUCTION

Itiḥab-e-Tajaweef-e-Anaf is composed of three words “*Itiḥab*” means “Inflammation” and “*Tajaweef*”. means “cavities within organs” and “*Anaf*” means “Nose”.^{1,2} In Ancient Unani books there is no specific description of *Warm-e- Tajaweef-e-Anaf* (Sinusitis), but the features described by the ancient Unani physicians under the chapter of *Nazla haar* and *Nazla barid* in various Unani books correspond with the signs and symptoms of *Warm-e-Tajaweef-e-Anaf haad wa muzamin* (Acute and Chronic Sinusitis)³. *Buqrat* (Father of Medicine) describes *Nazla wa Zukam* as two different words. “*Zukam*” is the *Nazla* (Coryza) of the nasal mucosal lining and the *Nazla* is a state in which the nasal mucosa actually gets involved and is always associated with excessive nasal discharge”⁴. Most of the Unani physicians said that the *Balgham* (phlegm) dripping into the throat is known as *Nazla* and to the nose is known as *Zukam*^{5,6,7}.

As there is no specific description present in any Unani classical books regarding *Warm-e Tajaweef-e-Anaf*, any particular cause cannot be pen down, but we get description of various predisposing factors responsible for inflammation of *Tajaweef* (cavities) and *Majari* (ducts). *Ibn Abbas Majoosi* in his book *Kamil-us-Sana* has defined that *warm haar* and *warm barid* may affect the mucous membrane of the nose resulting in *tamaddud* (congestion) and *girani* (lethargy). In *warm haar* other symptoms like headache, body pain may be present while *warm barid* spares this^{8,9}. All the Unani physicians unanimously ascertain that the genesis of *Nazla* is related with extrinsic and intrinsic factors. The mucous membrane gets inflamed and produces secretions which may be *raqueeq* (watery) or *ghaleez* (viscid), *garam* (hot), *Lazae* (irritative) and *barid* (cold) as per causative factors¹⁰.

Itiḥab-e-Tajaweef-e-Anaf Muzmin (Chronic Sinusitis) is affecting a large population worldwide. In a study it was observed that about 134 million Indians suffer from *Itiḥab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis), every year which is more than double the number of diabetic patients in India¹¹.

According to Modern Medicine, paranasal sinuses can be divided as Frontal Sinus, Maxillary Sinus, Ethmoidal Sinus and Sphenoidal Sinus. Any inflammation of the mucosa of these paranasal sinuses is termed as *Warm-e-Tajaweef-e-Anaf* (Sinusitis) . The term Sinusitis is specially applied to an inflamed condition that occurs in the spaces or cavities in the bones of

face or skull¹². The mucosal inflammation of paranasal sinuses is termed Sinusitis. It may be Acute or Chronic. The Acute inflammation of the sinus mucosa commonly follows an attack of Acute Rhinitis as in common cold or influenza when the bacteria invade as the secondary organism. The Chronic Sinusitis is usually the result of incompletely resolved Acute Sinusitis. It may follow insidiously after repeated attacks of common cold or tooth infection which causes chronic changes in sinus mucosa¹³.

Sinusitis is one of the most frequently overlooked disease in clinical practice. It is mainly caused by bacteria, viruses and fungi. It is also associated with anatomical abnormalities of the nose. Chronic Sinusitis is more common in cold & wet climates. Changes in environmental factors may predispose to infection. Nutritional deficiency, fatigue, poor physical fitness and general systemic diseases are important considerations in the aetiology of Sinusitis.^{12,13,14,15,16}.

The symptoms are variable, may be general or localized to the ear, nose and throat. Clinical features of Chronic Sinusitis are often vague and similar to those of Acute Sinusitis but of lesser severity. Purulent or Mucopurulent nasal discharge is the commonest complaint. Chronic Sinusitis is characterized by nasal obstruction, nasal discharge, abnormalities of smell, headache, sneezing etc.^{14,15,16,17}. The signs and symptoms include pain, nasal discharge, post nasal drip may be seen on the upper soft palate on posterior rhinoscopy, pressure on tapping over the anterior wall of antrum produces pain, redness and edema of cheek commonly seen in children. The lower eyelid may be puffy and patient complain of abnormality of smell and diminished smell(hyposmia)^{18,9,20}.

In Modern Medicine, the use of antibiotics, decongestants and anti-histamines provides symptomatic relief but does not cure all the patients. Whereas Unani Medicine boasts a trove of safe and effective medications with very few side effects. Local treatment consists of repeated inhalations, *Inkebab* (fomentation) and local applications of *Muhallil-e-auram* (anti-inflammatory) agents which may liquefy the viscid humours that block the ostium of the Sinusitis. Several Unani single and compound drugs are being used and claimed by Unani physicians to be beneficial in management of *Ittihab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis).

Banafsha (*Viola odorata*) is an important drug of the Unani System of Medicine belonging to family Violacea . It is commonly known as Sweet Violet, English Violet, Common Violet, Florist's Violet or Garden Violet²¹. *Banafsha* posses *Muhallil* (Anti-inflammatory activity), *Mulattif* (Demulcent activity), *Munaffis e balgham* (Expectorant), *Mushil e safra* (Purgative for bile), *Musaffi e dam* (blood purifier), *Musakkin e auja* (Sedative) *Munawwim* (Hypnotic), *Mughazzi* (Nutritive), *Muarriq* (Diaphoretic), *Dafa e humma* (Antipyretic), Jazib (Absorbent) and *Muzalliq* (lubricant). As *Banafsha* possesses above mentioned properties, it has been used in the present study to reduce the sign and symptoms of Chronic Sinusitis²².

Material and Methods

Study design

An open observational clinical study was carried out in the of Dept. of *Moalajat*, Z.V.M. Unani Medical College & Hospital, Pune from 2013-2016. The research protocol was approved by Institutional Ethical Committee prior to its commencement. Sixty diagnosed patients were included in the study after obtaining the consent form. They were informed about the disease, the examination to be performed and the type of treatment to be given.

Inclusion Criteria

- Patients attending hospital OPD and having clinical features of Sinusitis and diagnosed by pathological investigation and X-ray PNS (Water's view).
- Patients in the age group from 15-60 years irrespective of gender, whose presenting complaints were headache, sneezing, tenderness of sinuses, nasal discharge and nasal obstruction.
- Only the patients of open type Frontal and Maxillary Sinusitis.

Exclusion Criteria

- Patients with a known history of systemic diseases like diabetes, endocrine disorders, renal failure, tuberculosis, chronic heart disease etc.
- Pregnant and lactating mothers.

- Patients having nasal polyp, any malignant growth in sinus and brain abscess due to complicated Chronic Sinusitis.

Diagnostic criteria

- For the diagnosis of *Iltihab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis), history, clinical examination and biochemical investigations kept under consideration.
- Chief complaints, history of present illness were interrogated, general and systematic examination were done in detail and recorded in the case report form.

Procedure of study

The individual assessment was carried out on the basis of history, physical, general & systemic examination and the patients who were fulfilling the inclusion criteria were included in the clinical trial after getting the written consent from the patient. All the patients were informed about the duration of the study, the expected advantages and disadvantages of the drug. The clinical examinations were carried out, as well as subjective and objective parameters were noted in case report form. The complete specific laboratory investigations were done & noted in the patient's case report form at 0-day, 7th day, 14th day and 21st day. After completion of study, the data was tabulated and statistically analyzed by calculating the mean and standard deviation followed by applying paired 't' test for the observations recorded before and after the treatment.

Intervention

The *Safoof* prepared from *Gul-e-Banafsha* was given 5 grams orally twice daily for 21 days.

Result

In this study, 60 patients of different age groups suffering from Chronic Sinusitis (*Iltihab-e-Tajaweef-e-Anaf Muzmin*) were treated, with *Safoof-e-Banafsha* for 21 days with every 7th day follow-up. The laboratory and radiological investigation were carried out before and after treatment. All findings were analyzed statistically and tabulated. The results were observed in different parameters.

Age: The present study reflects a higher incidence of Chronic Sinusitis in the age group of 25-34 years i.e., 53.3%. (Table No.1)

Table 1: Age distribution of the cases studied (n=60)

Age Group (years)	No. of cases	% of cases
<25.0	19	31.7
25.0 – 34.0	32	53.3
35.0+	9	15.0
Total	60	100.0

Sex: In this clinical study it was found that the incidence of Chronic Sinusitis was more in males (70%) as compared to females (30%). (Table No.2)

Table 2: Sex distribution of the cases studied (n=60)

Sex	No. of cases	% of cases
Male	42	70.0
Female	18	30.0
Total	60	100.0

Values are n (% of cases).

Effect on objective parameter

Radiological response, X-Ray's PNS Water's View: The average X-Ray PNS Score is significantly higher at visit 1 compared to visit 4 (P- value <0.001) (Table No.3)

Table 3a: The distribution of improvement in objective parameters (X-RAY PNS Score) studied (n=60).

Parameter	Visit 1 (n=60)	Visit 4 (n=60)
X-Ray PNS Score	1.4 ± 0.06	0.4 ± 0.07
% Change	0%	75.0%

Values are Mean ± Standard error of mean (SEM).

Table 3b: The statistical comparison of improvement in objective parameters (X-RAY PNS Score) studied (n=60).

Comparisons (Pair-wise)	Test Statistic (Wilcoxon's Signed Rank)	P-value	Significance
Visit 1 v Visit 4	6.687	0.001***	Highly Significant

*P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS: Statistically Non-Significant.*

Effect on Subjective Parameters:

Headache

The gradin0g of headache significantly improved at visits 2, 3 and 4 compared to visit1(P-value <0.001)

Table 4a: The distribution of improvement in Headache (n=60).

Headache	Visit 1 (n=60)		Visit 2 (n=60)		Visit 3 (n=60)		Visit 4 (n=60)	
	n	%	n	%	n	%	n	%
No headache	0	0.0	1	1.7	12	20.0	39	65.0
Mild	4	6.7	37	61.7	44	73.3	21	35.0
Moderate	47	78.3	21	35.0	4	6.7	0	0.0
Severe	9	15.0	1	1.7	0	0.0	0	0.0

Values are n (% of cases).

Table 4b: The statistical comparison of improvement in Headache (n=60).

Comparisons (Pair-wise)	Test Statistic (Wilcoxon's Signed Rank)	P-value	Significance
Visit 1 v Visit 4	6.687	0.001***	Highly Significant

*P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS: Statistically Non-Significant.*

Nasal Discharge

Table showing the grading of nasal discharge at visits 2, 3 and 4 compared to visit-1 (P-value < 0.001)

Table 5a: Nasal Discharge (n=60).

Nasal Discharge	Visit 1 (n=60)		Visit 2 (n=60)		Visit 3 (n=60)		Visit 4 (n=60)	
	n	%	n	%	n	%	n	%
No Discharge	1	1.7	29	48.3	7	11.7	41	68.3
Mild	2	3.3	31	51.7	49	81.7	19	31.7
Moderate	49	81.7	0	0.0	4	6.7	0	0.0
Severe	8	13.3	0	0.0	0	0.0	0	0.0

Values are n (% of cases).

Table 5b: The statistical comparison of Nasal Discharge (n=60).

Comparisons (Pair-wise)	Test Statistic (Wilcoxon's Signed Rank)	P-value	Significance
Visit 1 v Visit 2	5.284	0.001***	Highly Significant
Visit 1 v Visit 3	7.101	0.001***	Highly Significant
Visit 1 v Visit 4	7.124	0.001***	Highly Significant

P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS:

Statistically Non-Significant.

Nasal Obstruction

Table showing the grading of nasal obstruction at visits 2, 3 and 4 compared to visit-1 (P-value<0.001)

Table 6a: Nasal Obstruction (n=60).

Nasal Obstruction	Visit 1 (n=60)		Visit 2 (n=60)		Visit 3 (n=60)		Visit 4 (n=60)	
	n	%	n	%	n	%	n	%
No Obstruction	0	0.0	15	25.0	36	60.0	49	81.7
Mild	30	50.0	38	63.3	22	36.7	11	18.3
Moderate	27	45.0	6	10.0	2	3.3	0	0.0
Severe	3	5.0	1	1.7	0	0.0	0	0.0

Values are n (% of cases).

Table 6b: The statistical comparison of improvement in Nasal Obstruction (n=60).

Comparisons (Pair-wise)	Test Statistic (Wilcoxon's Signed Rank)	P-value	Significance
Visit 1 v Visit 2	6.172	0.001***	Highly Significant
Visit 1 v Visit 3	6.589	0.001***	Highly Significant
Visit 1 v Visit 4	6.649	0.001***	Highly Significant

P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS:

Statistically Non-Significant.

Sneezing

The frequency of sneezing significantly reduced at visits 2, 3, and 4 compared to visit 1 (P-value <0.001)

Table 7a: Sneezing frequency (n=60).

Sneezing (No. of sneezes per day)	Visit 1 (n=60)		Visit 2 (n=60)		Visit 3 (n=60)		Visit 4 (n=60)	
	n	%	n	%	n	%	n	%
Very mild (<5)	1	1.7	11	18.3	31	51.7	44	73.3
Mild (6-15)	33	55.0	36	60.0	25	41.7	16	26.7
Moderate (16-25)	16	26.7	13	21.7	4	6.7	0	0.0
Severe (>25)	10	16.7	0	0.0	0	0.0	0	0.0

Values are n (% of cases).

Table 7b: The statistical comparison of reduction in frequency of Sneezing (n=60).

Comparisons (Pair-wise)	Test Statistic (Wilcoxon's Signed Rank)	P-value	Significance
Visit 1 v Visit 2	5.745	0.001***	Highly Significant
Visit 1 v Visit 3	6.726	0.001***	Highly Significant
Visit 1 v Visit 4	6.964	0.001***	Highly Significant

*P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS:*

Statistically Non-Significant.

Tenderness

The tenderness grading significantly improved at visits 2, 3, and 4 compared to visit 1
Tenderness grading (P-value <0.001)

Table 8a: Tenderness (n=60).

Tenderness	Visit 1 (n=60)		Visit 2 (n=60)		Visit 3 (n=60)		Visit 4 (n=60)	
	n	%	n	%	n	%	n	%
Grade 0	1	1.7	18	30.0	39	65.0	50	83.3
Grade 1	30	50.0	30	50.0	20	33.3	10	16.7
Grade 2	20	33.3	11	18.3	1	1.7	0	0.0
Grade 3	9	15.0	1	1.7	0	0.0	0	0.0

Values are n (% of cases).

Table 8b: The statistical comparison of improvement in Tenderness (n=60).

Comparisons (Pair-wise)	Test Statistic (Wilcoxon's Signed Rank)	P-value	Significance
Visit 1 v Visit 2	6.332	0.001***	Highly Significant
Visit 1 v Visit 3	7.038	0.001***	Highly Significant
Visit 1 v Visit 4	6.887	0.001***	Highly Significant

P-values by Wilcoxon's signed rank test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, ***P-value<0.01, ****P-value<0.001, NS: Statistically Non-Significant.

Discussion

Age

In the present study total 60 patients were studied, out of which the patients with age group <25 years were 19, i.e,31.7%, whereas the patients with age group 25-34 years were 32, i.e., 53.3% and the patients with age group 35-60 years were 9, i.e,15.0%. According to classical Unani textbooks, the age group having *Ghalba-e-balgham*, are the more sufferers of Sinusitis. The present study reflects the same thing. Here, out of three groups the group of 25-34 years are more sufferers of Chronic Sinusitis.

Sex

Among 60 cases, 42 were males i.e,70% and 18 were females i.e, 30%. According to ancient Unani physicians, females are more affected with *Itti hab Tajaweef-e-Anaf Muzmin*, but in the present study, the males are more than females which does not correlate with classical literature.

Effect on X-Ray (Water's View)

The present study reflects in radiological reference in X-Ray at visit 1 with an average mean of 1.4 whereas the average mean at visit 4 is 0.4. Comparing visit 1 with visit 4 we get p value 0.001 by Wilcoxon's Signed Rank. Hence p-Value is 0.001 which is less than 0.05 which is statistically significant. Hence the drug is effective in Chronic Sinusitis. (Table No.3a & 3b).

Effect on Subjective Parameter

Headache

According to grading of headaches, significant changes are found from first day to 21th day. 56 patients out of 60 have got complete relief, while 4 patients have remained with milder symptoms or none. Calculating Wilcoxon's Signed Rank test Value of visit 1 v/s visit 2, visit 1 v/s visit 3, visit 1 v/s visit 4 is 5.988, 6.76 & 6.891 respectively with p-Value 0.001. (Table No.4a & 4b).

Nasal Discharge

In this study 57 patients out of 60 have got complete relief. While 3 patients have remained with little symptoms. Calculating the p value by Wilcoxon's signed rank, comparing visit 1 v/s visit 4 is 0.001 which is less than 0.05, which is statistically significant. Hence the drug is effective in nasal discharge (Table No.5a & 5b).

Nasal Obstruction

30 patients out of 60 got complete relief, while 30 patients remained with mild symptoms. Calculating Wilcoxon's Value of Visit 1 v/s Visit 4, is 6.649 so the p-Value is 0.001 which is significant (Table No.6a & 6b).

Sneezing

26 patients out of 60 got complete relief, while 34 patients remained with mild symptoms. P value < 0.05 is considered to be statically significant (Table No.7a & 7b).

Tenderness

In this study 29 patients out of 60 got complete relief, while 31 patients remained with mild symptoms. Calculating the p value by Wilcoxon's signed rank test comparing visit 1 v/s visit 4 is 0.001 which is less than 0.05, which is statistically significant (Table No 8a & 8b).

CONCLUSION

Warm-e-Tajaweef-e-Anaf Muzmin (Chronic Sinusitis) is a major healthcare problem that affects a large chunk of the population. Unani System of Medicine offers a wide range of herbal drugs that are effective in treatment of *Nazla*. In the light of above findings and discussion, it is concluded that *Safoof-e-Banafsha* is safe and effective in the cases of Chronic Sinusitis. This drug can be used for longer duration. Radiological examination, calculating Wilcoxon's value of visit 1 to visit 4 is 6.687 with P value is 0.001 which is highly significant. In subjective parameters, improvement was very significant. The p-Value in all is less than 0.05, which suggests that the drug is effective in nasal obstruction, headache, sneezing, tenderness and nasal discharge. Since *Safoof-e-Banafsha* has proved to be highly effective in this study, it is suggested to conduct the research over a large sample to know its benefits and side effects if any.

Acknowledgment




The authors are thankful to the patient who cooperated during the treatment period.

Conflict of interest

There is no conflict of interest to declare.

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