



A Prospective Open Label Randomized Clinical Study of Compound Unani Formulation (*Ustukhuddoos, Filfil Siyah, Aslussoos*) in the Management of *Iltihab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis).

Md Zahid Arfi¹, Md Razi Ahmad², Md Najibur Rahman³, *Md Tanwir Alam⁴.

1.PG Scholar, Dept. of Moalajat, ZVM Unani Medical College & Hospital Pune.

2.Assistant Professor, Dept. of Niswa wa Qabalat, Govt. Tibbi College & Hospital, Patna.

3.Assistant Professor, Dept. of Moalajat, Govt. Tibbi College & Hospital, Patna.

4.Assistant Professor, Dept. of PSM, Govt. Tibbi College & Hospital, Patna.

ABSTRACT

Tajaweef-e-Anaf (Sinusitis) has tremendous impact on public health. It is the 5th known case of population^{16,17}. Under such circumstances, the Unani medicine has proven its own importance regarding its efficacy, cost and minimal side effects. The present study was designed as an open label randomized clinical trial in successive patients with chronic sinusitis diagnosed on presentation, history and investigations. Sixty diagnosed patients of age between 15-60 years. Who belongs to inclusion criteria were registered, and compound Unani formulation (*Ustukhuddoos, Filfil Siyah, Aslussoos*) is given for 45 days. Complete physical examination & investigations of patients were done and follow-up planned prior of trial, 15th 30th day and at the end of trial. Subjective objective and safety parameter recorded. On objective parameters, there are two sub headings, pathological investigation and radiological examination. In Radiological examination, Calculating by Chi-square p-Value is 0.001 which is significant. While in pathological investigation in TLC, Lymphocyte, Eosinophils “P” value is 0.001, which is very significant. Haemoglobin “P” value is 0.517 and Monocyte, “P” value 0.088 which is not significant.

Keywords: *Tajaweef-e-Anaf; Ustukhuddoos; Filfil Siyah; Aslussoos; Unani Medicine.*

*Corresponding Author Email: tanveernium3133@gmail.com

Received 10 September 2020, Accepted 20 September 2020

Please cite this article as: Alam MT *et al.*, A Prospective Open Label Randomized Clinical Study of Compound Unani Formulation (*Ustukhuddoos, Filfil Siyah, Aslussoos*) in the Management of *Iltihab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis).. American Journal of Pharmacy & Health Research 2020.

INTRODUCTION

All paranasal sinuses are prone to inflammation and one or more than one sinus may be involved in a single patient. Majority of cases involves more than two sinuses. Most commonly involved are maxillary sinuses. With the same time extension and frequency of ethmoid, frontal, sphenoid sinuses. Sinusitis may be caused by bacteria, viruses and fungi. Sinusitis may be associated with anatomical abnormalities of nose like DNS. Sinusitis affects all groups of populations, mainly of lower age group, and has sometimes the risk of morbidity. Medical management as offered by modern system of medicine consists of the use of antibiotics, decongestants and anti-histamines. But it does not cure all the patients, often necessitating surgical intervention (antral puncture and drainage), which too fails to provide irreversible cure to all patients. Patients of sinusitis have become dependent on painkillers, which may cause hazardous side effects on prolong use. In spite of recent advances in medicine, chronic sinusitis still remains one of the most common and difficult clinical problem because of its complications like brain abscess and otitis media etc ^{18,19,20,21}.

Under such circumstances, the Unani medicine has proven its own importance regarding its efficacy, cost and minimal side effects. The general treatment of chronic sinusitis consists of moderating with altered humours, excretion of excessive and altered *balgham* and subsiding the local inflammation. For this purpose, the medicines used in Unani system have properties like, *Mulattif* (demulcent), *Munzij* (deobstruent), *Munaffis-e-Balgham* (expectorant) and *Muhallil-e-Auram*. (Anti-inflammatory). Thus, selection of compound Unani formulation (*Ustukhuddoos*, *Filfil Siyah*, *Aslussoos*) is supported by unani literatures, which claim that it has good effect in the management of *Iltihab-e-Tajaweef-e-Anaf Muzmin*.

The present study was designed as an open label randomized clinical trial in successive patients with chronic sinusitis diagnosed on presentation, history and investigations. Sixty diagnosed patients of age between 15-60 years. Who belongs to inclusion criteria were registered, and compound Unani formulation (*Ustukhuddoos*, *Filfil Siyah*, *Aslussoos*) is given for 45 days. Complete physical examination & investigations of patients were done and follow-up planned prior of trial, 15th, 30th day and at the end of trial. Subjective objective and safety parameter recorded. Complication and side effects treated accordingly and data collected. An official approval of study proposal was taken by the College and Hospital ethical committee; later on, by MUHS, Nashik (M.S.) before starting the trial. The statistical analysis of data has been done with the help of computer software "Statistical Package for Social Sciences". Test of significant calculated by using paired "t" test.

MATERIALS AND METHOD

The present clinical study entitled as “Clinical Study of Compound unani formulation (*Ustukhuddoos, Filfil Siyah, Aslussos*) in the Management of *Iltihab-e-Tajaweef-e-Anaf Muzmin* (Chronic Sinusitis)”, was conducted at research institute, under the department of *Moalajat*. Before starting the clinical trial, the proposal was kept before ethical committee. Once the ethical clearance was sought, clinical study was started by enrolling eligible patients by open trial.

Criteria for selection of cases

Inclusion criteria:

1. Patients attending institute’s general hospital OPD and have clinical features of sinusitis and diagnosed by Xray were included for clinical trial.
2. Age group from 15-60 years of either gender was included in clinical trial.
3. History of occupation & their life style (sedentary life style, worker or labour).
4. History of socio-economic status and habits (particularly dietary habits, smoking and exercise).
5. In case of females, only non-pregnant females.

Exclusion criteria:

1. Patients suffering from any other systemic diseases like diabetes, endocrine disorders, chronic heart disease etc.
2. Pregnant women were excluded from study.
3. Patients having nasal polyp, any malignant growth in sinus, brain abscess due to complicated chronic sinusitis, have not been taken for clinical studies.

Withdrawal criteria:

1. Failure to follow the protocol.
2. Any adverse reaction or adverse event.
3. Any Idiosyncratic reaction.
4. Any life-threatening systemic disorder or pregnancy is revealed during study.

PARAMETER OF EVALUATION:

The assessment of efficacy in the patients was based on the following two types of parameters.

Subjective parameters

Objective parameters

Subjective Parameter:

1. Nasal Obstruction
2. Nasal Discharge

3. Headache
4. Sneezing
5. Malaise
6. Hypertrophied Nasal Mucosa
7. Deviated Nasal Septum

Objective Parameter:

1. X-ray PNS (Water's view).
2. Heamogram (a) Haemoglobin (b) TLC (c) Lymphocyte (d) Neutrophil (e) Eosinophils (f) Monocyte

Of the above investigations, X-ray PNS (Water's view) was quite essential to diagnose chronic sinusitis. All investigations were done before and after the study.

Sample size:

Total number of 60 patients were included in the study of either gender by random selection and belongings to inclusion criteria.

Study Procedure:

The individual assessment was carried out on the basis of history, physical, general, systemic examination. And the patients who are full fill the inclusion criteria and also given written consent were included in the clinical trial. The *Safoof* prepared from *Ustukhuddoos*, *Filfil Siyah*, *Aslussesos*- 3 grams two times a day for 45 days. All the patients were informed about the duration of the study, expected disadvantages and advantages during consumption of the drug. Observations were noted down in the case report form. Patients were advised to come regularly P.G. Dept. of *Moalajat* for their follow up under strict supervision. The clinical examinations were carried out and general, physical examinations as well as subjective and objective parameters were noted in C.R.F. The complete specific laboratory investigation findings were done & noted in the patient's case report form at 0-day, 15th day, 30th day and 45th days. 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. Following formula were used in the calculations. The drug is very cost effective with excellent result.

RESULTS AND DISCUSSION

Effects on Hemogram

Parameters	Visit 1 st	Visit 4 th	Visit 1 st vs Visit 4 th		
			"T" value	DF	"P" value
TLC	11.0 ± 1.2	8.9 ± 1.7	9.521	59	0.001 (Significant)
Neutrophils	90.6 ± 5.1	57.9 ± 14.4	19.470	59	0.001 (Significant)
Eosinophils	7.1 ± 1.1	3.5 ± 0.6	20.676	59	0.001 (Significant)
Monocytes	2.4 ± 1.1	2.3 ± 0.8	1.734	59	0.088 (Non-Significant)
Lymphocytes	41.7 ± 4.3	32.7 ± 3.1	21.425	59	0.001 (Significant)
Haemoglobin	11.8 ± 1.5	11.9 ± 1.3	-0.652	59	0.517 (Non-Significant)

Effects on X-Ray PNS

X-Ray PNS Grading	Visit 1 st	Visit 4 th	Visit 1 v/s Visit 4		
			Chi-Square value	DF	"P" value
Grade 0	00	45 (75.0%)	72.8	3	0.001
Grade 1	49 (81.7%)	14 (23.3%)			(Significant)
Grade 2	10 (16.7%)	1 (1.7%)			
Grade 3	1 (1.6%)	0			

Effects on Headache

Headache Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	"P" value
Nil	00	2 (3.3%)	13 (21.7%)	39 (65.0%)	112.7	3	0.001
Mild	2 (3.3%)	33 (55.0%)	43 (71.7%)	21 (35.0%)			(Significant)
Moderate	54 (90.0%)	25 (41.7%)	04 (6.6%)	00			
Severe	4 (6.7%)	00	00	00			

Effects on Nasal discharge

Nasal Discharge Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	"P" value
Nil	00	00	8 (13.3%)	42(70.0%)	112.8	3	0.001
Mild	2 (3.3%)	29 (48.3%)	48 (80.0%)	18(30.0%)			(Significant)
Moderate	50 (83.3%)	31 (51.7%)	4 (6.7%)	00			
Severe	8(13.4%)	00	00	00			

Effects on Nasal Obstruction

Nasal Obstruction Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	"P" value
Nil	00	18 (30.0%)	39 (65.0%)	51 (85.0%)	92.1	3	0.001
Mild	31 (51.7%)	39 (65.0%)	21 (35.0%)	9 (15.0%)			(Significant)
Moderate	28 (46.7%)	3 (5.0%)	00	00			
Severe	1 (1.6%)	00	00	00			

Effects on sneezing

Sneezing Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	“P” value
Nil	1 (1.7%)	11(18.3%)	31(51.7%)	45(75.0%)	75.2	3	0.001(Significant)
Mild	32(53.3%)	35(58.3%)	25(41.7%)	15(25.0%)			
Moderate	16(26.7%)	14(23.4%)	4 (6.6%)	00			
Severe	11(18.3%)	00	00	00			

Effects on Malaise

Malaise Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	“P” value
Nil	1 (1.7%)	19(31.7%)	41(68.3%)	54(90.0%)	95.9	3	0.001 (Significant)
Mild	32(53.3%)	30(50.0%)	19(31.7%)	6(10.0%)			
Moderate	19(31.7%)	11(18.3%)	00	00			
Severe	8 (13.3%)	00	00	00			

Effects on Hypertrophied Nasal Mucosa

Hypertrophied Nasal Mucosa Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	“P” value
Nil	49 (81.7%)	49(81.7%)	49(81.7%)	57(95.0%)	05.2	01	0.043(Significant)
Mild	11 (18.3%)	11(18.3%)	11(18.3%)	3(5.0%)			
Moderate	00	00	00	00			
Severe	00	00	00	00			

Effects on Deviation of Nasal Septum

Hypertrophied Nasal Mucosa Grading	Visit 1 st	Visit 2 nd	Visit 3 rd	Visit 4 th	Visit 1 v/s Visit 4		
					Chi-Square value	DF	“P” value
Nil	47(78.3%)	47(78.3%)	47(78.3%)	58(96.7%)	09.2	01	0.004 (Significant)
Mild	13(21.7%)	13(21.7%)	13(21.7%)	13(21.7%) 2 (3.3%)			
Moderate	00	00	00	00			
Severe	00	00	00	00			

CONCLUSION

Sinusitis is a major health problem throughout the world. In unani system of medicine also claimed the number of single and compound drugs to cure the *Iltihabe Tajaweef-e-Anaf Muzmin* without causing any side effects. Therefore, it is an important need to provide safe and effective drug from Unani system of medicine for the management of Sinusitis. So, keeping the fact in mind, the study entitled “A Prospective Open Label Randomized Clinical Study of Compound Unani Formulation (*Ustkhuddoos, Filfil Siyah, Aslussoos*) in the Management of *Iltihab-e-Tajaweef-e-Anaf Muzmin*

(Chronic Sinusitis)". All patients received *Safoof* prepared from the drugs 03-gram BD. As evidence of observation result and discussion of the study following conclusion can be drawn; On objective parameters, there are two sub headings, pathological investigation and radiological examination. In Radiological examination, Calculating Chi-square Value of Visit 1 v/s Visit 4 is 72.8 with df 3 than the p-Value is 0.001 which is significant. While in pathological investigation readings are follows. In haemoglobin T value is -0.652 with 59 df than P value is 0.517 which is not significant. In Monocyte, T value is 1.734 with 59 df and P value by paired 't' test is 0.088 which is not significant. In TLC, T value is 9.521 with 59 df and P-value is 0.001 which is significant. In Lymphocyte, T value is 21.425 with 59 df and P value by paired 't' test is 0.001. In Eosinophils T value is 20.676 with 59 df and P value by paired 't' test is 0.001 which is significant. In Neutrophil, T value is 19.470 with 59 df and P value by paired 't' test is 0.001 which is significant. This result suggests that the effect of drug is there on X-ray, Lymphocyte, Neutrophil, Eosinophils and TLC. After Intervention the study reveals that the *safoof* does not act on Haemoglobin and Monocyte.

On objective parameters, improvement is very significant. All the parameters in each intervention groups are significant. In Nasal Obstruction Chi-square Value 92.1 with df 3 than the p Value is 0.001, In Nasal Discharge, 112.8 with df 3 than the p-Value is 0.001, In Headache, is 112.7 with df 3 than the p Value is 0.001, In Sneezing, 75.2 with df 3 than the p-Value is 0.001, In Malaise, 95.9 with df 3 than the p-Value is 0.001, In Hypertrophied Nasal Mucosa, 5.2 with df 1 than the p-Value is 0.043, In Deviated Nasal Septum, 9.2 with df 1 than the p Value is 0.004 that is extremely significant. This result suggests that the effect of drug on the Nasal Obstruction, Nasal Discharge, Headache, Sneezing, Malaise, Hypertrophied Nasal Mucosa and Deviated Nasal Septum. Therefore, it can be concluded that the drug formulation is safe and effective in the cases of Sinusitis. Finally, as with any analysis, the potential for publication bias is of concern. Visual inspection of our analysis funnel plot could not rule out for publication bias.

ACKNOWLEDGEMENT

Authors acknowledge all the scholar, writer and scientist whose reference has been cited in this review article.

REFERENCES

1. Bhargova KB, Bhargova SK, Shah TM. A Short Text Book of ENT Diseases, 6th edi., Usha Publishers, Mumbai. 180-189
2. Schlossberg D. Infection of the Head and Neck, Springle-Verlag Publisher, New York. 81-87

3. Arend, Armitage, Clemmons *et al.* Cecil Text Book of Medicine, 23rd edi., Philadelphia, Saunders Elsevier. 2007; Vol 1: 2875
4. Kumar P and Clark M. Clinical Medicine, 6th edi., Elsevier Saunders Publication, Philadelphia, USA: 1158
5. Drake RL, Vogl W. Grays Anatomy for Students. Elsevier Saunders Publication, Philadelphia, USA 2005: 970-975.
6. Nawaz M. Evaluation of efficacy of Unani formulation in the management of *Warne Tajaweef-e-Anaf*, Dissertation submitted to Rajiv Gandhi University, Banglore 2007: 3-4, 9-18.



AJPHR is
Peer-reviewed
monthly
Rapid publication
Submit your next manuscript at
editor@ajphr.com / editor.ajphr@gmail.com