

# Evaluation of Efficacy of Unani Compound Formulation “Sinugard Granules” in the Management of Warm-e-Tajaweef-e-Anf (Sinusitis)-A Preliminary Study

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## Abstract

The mucosal inflammation of the Paranasal sinuses may be acute or chronic process. 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 secondary organisms (Dhingra, 2008). The effective treatment to manage this clinical entity is available in modern medicine but there is a need of the time to develop a safe and curative treatment in the Indian system of medicine.

Hence the objective of the present study is to evaluate the efficacy of Unani formulation ‘Sinugard Granules’. The study was open single group uncontrolled clinical trial. In the present study forty cases of 13 to 57 years of age who were clinically diagnosed were enrolled in the study for 10 days from Moalejat and Otorhinolaryngology OPD, Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh. The patients were treated with half sachet of ‘Sinugard Granules’ twice a day with lukewarm water. All the patients were assessed for subjective parameters. The study revealed that the Unani formulation has given good response on nasal congestion, tenderness and nasal discharge. Therefore, it can be concluded that the compound Unani Formulation ‘Sinugard Granules’ can be used for the treatment of Warm-e-Tajaweef-e-Anf (Sinusitis).

**Key Words:** Warm-e-Tajaweef-e-Anf, Ustukhuddus, Asalassus, Badiyan, Eucalyptus oil

## Introduction

Paranasal sinuses are air-containing cavities in certain bones of skull. They are four on each side. Paranasal sinuses are lined by mucous membrane which is continuous with that of the nasal cavity through the ostia of sinuses. Paranasal sinuses develop as outpouchings from the mucous membrane of lateral wall of nose (Maqbool, 2002).

In ancient Unani literature, Warm-e-Tajaweef-e-Anf (sinusitis) is not described as such but when we go through the definitions of Nazla wa Zukam (Coryza or common cold) these seem to be quite similar to the clinical features of sinusitis (Arzani, 1956). Therefore, while laid down the principles of treatment of Warm-e-Tajaweef-e-Anf we may take etiopathogenesis of Nazla wa Zukam into consideration and treat this condition accordingly.

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The present study was carried to see the efficacy of *SINUGARD GRANULES* in Warm-e-Tajaweef-e-Anf with regards to amelioration of symptoms and signs. Although several allopathic drugs are available to treat the sinusitis but their use is hindered by adverse effects of such drugs. Therefore, we felt the necessity to find an alternative treatment in Indian system of Medicine, which could be used for a prolong interval of time without any serious complication.

### Material and Methods

The present study was carried out in Moalejat and Otorhinolaryngology OPD in Ajmal Khan Tibbiya College Hospital, Aligarh Muslim University, Aligarh. The forty patients of either sex between the age group 13 to 57 years were selected whose presenting complaint was headache, facial pain, tenderness, nasal discharge and nasal congestion. Only the patients of open type frontal and maxillary sinusitis were included in this study. The diagnosis was made on the basis of history and clinical examination.

Those suffering from Diabetes Mellitus, Features of toxæmia, complications of sinusitis or who had taken any form of treatment especially antibiotics were excluded from this study. For every patient informed consent was taken.

Patients subjected for the clinical trial were given half sachet of *SINUGARD GRANULES* twice a day for a period of 10 days. The patients were followed on every 5<sup>th</sup> day.

Each sachet of *SINUGARD* contains 2 grams of granules and has following ingredients.

Name of ingredient	Quantity
<i>Lavandula stoechas</i> L. (Ustukhuddus)	550 mg
<i>Glycyrrhiza glabra</i> L. (Asalassus)	550 mg
<i>Foeniculum vulgare</i> Mill. (Badiyan)	550 mg
Menthol	60 mg
Eucalyptus oil	40 ml
Cane sugar	250 mg

### Results and Observations

There was significant improvement in the subjective parameters except in the headache and facial pain.

The findings of demographic and subjective parameters were as follows.

During the course of study, patients were divided into five age groups viz. 13-21 years, 22-30 years, 31-39 years, 40-48 years, 49-57 years. It was observed that maximum number of cases i.e. 14 cases (35.0%) belong to the age group 13-21 years. 13 cases (32.5%) fell in the age group 22-30 years, 4 cases (10.0%) in the age group 31-39 years, 6 cases (15.0%) in the age group 40-48 years and 3 cases (7.5%) in the age group 49-57 years.

Among the forty patients 25 cases (62.5%) were males, while 15 cases (37.5%) were females. (Table-1)

**Table 1 :** Showing Distribution of Patients According to Age and Sex

Total No. of Cases – 40

Age group (in years)	Number and % age of Males	Number and % age of Females	Total number and % age
13 – 21	10(25.0)	4(10.0)	14(35.0)
22 – 30	8(20.0)	5(12.5)	13(32.5)
31 – 39	3(7.5)	1(2.5)	4(10.0)
40 – 48	2(5.0)	4(10.0)	6(15.0)
49 – 57	2(5.0)	1(2.5)	3(7.5)
Total	25(62.5)	15(37.5)	40(100.0)

Patients were divided into five categories according to their occupation, student, service, labour, business and housewife. The number of cases falling in each category was 16 (40%), 6(15%), 5 (12.5%), 4(10.0%) and 9 (22.5%) respectively. Thus it was observed that maximum number of patients belong to students followed by housewives and service class. (Table-2)

**Table 2 :** Showing Distribution of Patients According to their occupation

Total No. of Cases – 40

Occupation	Number of Patients	Percentage
Student	16	40.0
Service	6	15.0
Labour	5	12.5
Business	4	10.0
Housewife	9	22.5
Total	40	100.0

Patients were divided into three groups on the basis of site of infection, frontal, maxillary, frontal and maxillary both. Maximum cases were found of frontal sinusitis i.e. 27 cases (67.5%) followed by 7 cases (17.5%) of maxillary sinusitis and 6 cases (15.0%) of frontal accompanied with maxillary sinusitis. (Table-3)

**Table 3:** Showing Distribution of Patients According to Site of Infection

Total No. of Cases – 40

Site	Number of Patients	Percentage
Frontal	27	67.5
Maxillary	7	17.5
Frontal+Maxillary	6	15.0
Total	40	100.0

The subjective parameters viz. headache, facial pain, tenderness, nasal discharge and nasal congestion were taken into consideration during the study. Out of 40 cases, facial pain, tenderness, nasal discharge and nasal congestion was found in 32 cases, 26 cases, 28 cases and 9 cases respectively, while headache was the main complaint in all the cases. At the end of study, it was observed that headache, facial pain, tenderness, nasal discharge and nasal congestion was improved by 57.5% (23 cases), 53.12% (17 cases), 69.23% (18 cases), 67.85% (19 cases) and 77.77% (7 cases) respectively. (Table-4)

**Table 4 :** Showing Effect of Drugs on Clinical Features of Sinusitis

Total No. of Cases – 40

Clinical Features	Follow-Up (in days)				
	Before Treatment	After Treatment			
	0 day	5th day		10th day	
	Total No. of Patients	No. of Patients	Improved % age	No. of Patients	Improved % age
Headache	40	22	45.00	17	57.50
Facial Pain	32	22	31.25	15	53.12
Tenderness	26	16	38.46	8	69.23
Nasal Discharge	28	16	42.86	9	67.85
Nasal Congestion	9	4	55.55	2	77.77

## Discussion

In the present study, the efficacy of *SINUGARD GRANULES* was evaluated over a period of 10 days on the basis of improvement in the subjective parameters.

While analyzing the age group the patients were divided into five age groups. It was observed that maximum number of cases i.e. 14 (35.0%) belong to age group 13-21 years. It is well synchronized with the fact that Sinusitis usually starts in the adolescent age group (Ballyntyne,1978).

During the study, students dominated followed by housewives. It may be due to high level of awareness among the students about this disease and secondly hospital is situated in the vicinity of university campus. Housewives get exposed to dust and various allergens while doing house hold work, which may triggers the development of Sinusitis (Dhingra, 2008).

While distributing the patients according to site of infection, cases of frontal sinusitis were more than the maxillary one and it is contradictory to the text in which maxillary sinusitis is more common than frontal (Maqbool, 2002).

When the distribution of patients according to their clinical presentation was studied, it was found that the most consistent presentation was headache in all the cases while facial pain in 32 cases, Nasal discharge in 28 cases, Tenderness in 26 cases and Nasal congestion in 9 cases was recorded.

At the end of study, maximum benefit was observed in the Nasal congestion i.e. 77.77% improvement. Anti-inflammatory property of Ustukhuddus (Baghdadi, 2005, Hakim, 1924, Anonymous, 1992) and Aslusoos (Kritkar, Basu, 1996) may be attributed to this effect of drug. Glycyrrhizin inhibited thrombin induced platelet aggregation which indicates anti-inflammatory activity ([www.krishnaherbals.com](http://www.krishnaherbals.com)). Nasal congestion was also improved due to the presence of menthol in the formulation because most of menthol's uses are related to its stimulation of the cold receptors. This property makes menthol to produce a cooling effect, which help to relieve the congestion ([www.wisegeek.com](http://www.wisegeek.com)). Moreover, it is used in pharmaceutical preparations to disguise the taste of evil-smelling and unpleasant drugs (Chopra, 1958).

There was 67.85% improvement in the patients of Nasal discharge, which may be due to the antiseptic property of Ustukhuddus (Ahmad, 1985), Aslusoos (Rastogi, 1985-89) and eucalyptus oil. Cineole (eucalyptol) is the most important ingredient of eucalyptol oil from the medical point of view. Australol and cryptol have also been found to be efficient antiseptic (Chopra, 1958).

The headache, facial pain and tenderness were improved by 57.50%, 53.12% and 69.23% respectively at the end of study. Analgesic property of Ustukhuddus, Aslusoos and Badiyan may be attributed to this effect of drugs (Anonymous, 1998, Gazrooni, 1887).

### **Conclusion**

This study shows the encouraging effect of Unani formulation with a potential in sinusitis management and no major adverse effects; and there is tolerance to this therapy. Further, long term studies to determine the relapse rate and the effect of Unani formulation on facial pain and headache along with standardization of active ingredients, purity and concentration are suggested.

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