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EFFECT OF HERBAL UNANI FORMULATION ON CHRONIC SINUSITIS

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ABSTRACT

Sinusitis is the inflammatory condition involving paranasal sinuses. The paranasal sinuses are air filled spaces in certain bone of skull and they are in direct communication with nasal cavity through their opening called ostia. The clinical manifestation of sinusitis is nasal discharge, headache, blocking of nose, changed nasal resonance, post nasal drip and pain with tenderness in affected sinus. It may be associated with fever occasionally. If the symptoms of sinus inflammation lasting >3 months, then the condition is called chronic sinusitis. Although there are so many unani single drugs and compound formulation are being claimed and used to treat and manage chronic sinusitis but here we are testing a well known and literary claimed formulation containing ingredients *Ustukhuddoos*, *Filfil Siyah* and *Aslussoos* for managing the various clinical sign & symptoms of chronic sinusitis.

KEYWORDS: Sinusitis; Unani medicine; Lavandula stoechas; Piper nigrum; Glycyrrhiza glabra.

INTRODUCTION

According to Ibn Sina, hot temperament people are much more prone to develop *Nazla* due to variation in environmental conditions and other extrinsic factors in comparison to the cold temperament people, who are more likely to develop Nazla due to intrinsic changes inside the body. [6,7]

Aristotle was the first ancient Unani physician who had described the "Pituitary Gland" as Infundibulum, which literally means funnel shaped organ. He stated that this funnel shaped organ drains one of the four cardinal humours i.e. the phlegmatic humour, which comes from the higher brain. Some part of this phlegmatic humour also drains in to nose. [8]

Most of the Unani physicians say that the phlegm dripping into the throat is known as *Nazla* and to the nose is known as *Zukam*. Differentiating the *nazla* and *zukam*, the father of medicine *Buqrat* (460-377B.C.) stated that, *zukam* is the *Nazla* (coryza) of nasal mucosal lining in which the nasal mucosa actually gets involved and always associated with excessive discharge. Several Unani physicians have described *Nazla* in lieu of the signs and symptoms of sinusitis, with its types *haad* and *muzmin*. [11,13,14]

The four pairs of sinuses (maxillary, frontal, ethmoidal, and sphenoidal) are partially enclosed cavities open to the nasal passages through small holes (ostea or meatus). The warm, moist sinus environment they create is speculated to aid olfaction, increase vocal resonance, reduce the bony weight of the skull, and protect intracranial structures from trauma. [15]

Unani medicine has proven its 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, demulcent, de-obstruent, 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 chronic sinusitis.

MATERIAL AND METHODS

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

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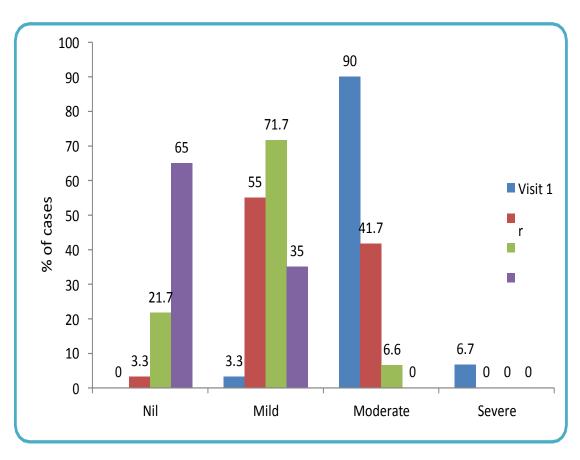
15-60 years. Who belongs to inclusion criteria were compound Unani registered, and formulation (Ustukhuddoos, Filfil Siyah, Aslussoos) is given for 45 days. Complete physical examination & investigations of patients were done and follow-up planned prior of trial, 15th, 30th day and at the end of trial. 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.

RESULTS AND ANALYSIS

In the present study, 60 patients of either sex of different age groups suffering from chronic sinusitis were treated, with a sincere and pious aim of providing the clinical efficacy of Compound Unani Formulation (Ustukhuddoos, Filfil Siyah, Aslussoos).

Effect on Subjective Parameter

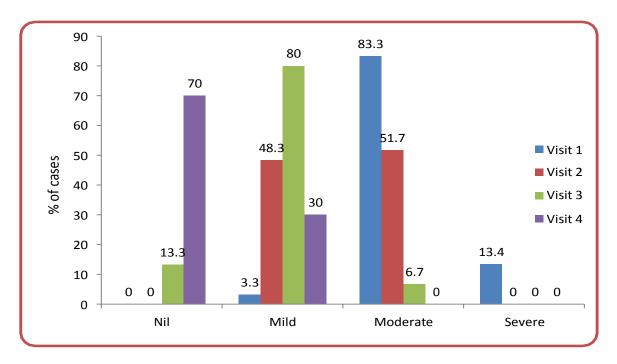
Effect on Headache: 0 day, the percentages are, severe 6.7%, Moderate 90%, mild 3.3% and asymptomatic 0%. On 15th day, the percentages are, sever 0%, Moderate 41.7%, mild 55%, and asymptomatic 3.3%. On 30th day, the percentages are, sever 0%, Moderate 6.6%, mild 71.7% and asymptomatic 21.7 and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 35%, and asymptomatic 65%. Calculating Chi-square Value of Visit 1 v/s Visit 4 is 112.7 with df 3 than the p-Value is 0.001 which is significant. According to grades of headache, significant changes are found from zero day to 40th day. 39 patients out of 60 have got complete relief. While 21 patients have remained with little symptoms. Chi-square value is 112.7 with df 3 and P< 0.05 is considered to be statically significant. Hence the drug is effective in nasal discharge.



Effect on Nasal Discharge: 0 day, the percentages are, severe 13.4%, Moderate 83.3%, mild 3.3% and asymptomatic 0%. On 15th day, the percentages are, sever 0%, Moderate 51.7%, mild 48.3%, and asymptomatic 0%. On 30th day, the percentages are, sever 0%, Moderate 6.7%, mild 80% and asymptomatic 13.3 and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 30%, and asymptomatic 70%. Calculating Chi-square Value of Visit 1 v/s Visit 4 is

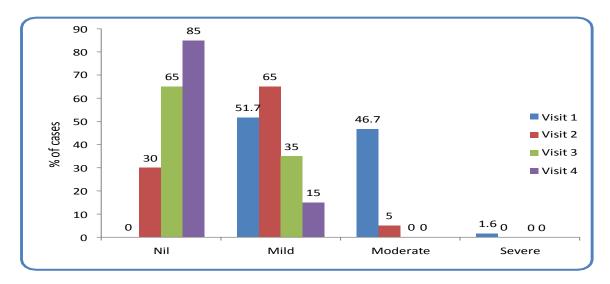
112.8 with df 3 than the p-Value is 0.001 which is significant. According to grades of nasal discharge, significant changes are found from zero day to 45th day. 42 patients out of 60 has got complete relief. While 18 patients have remained with little symptoms. Chi square value is 112.8 with df 3 and P< 0.05 is considered to be statically significant. Hence the drug is effective in nasal discharge.

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Effect on Nasal Obstruction: 0 day, the percentages are, severe 1.6%, Moderate 46.7%, mild 51.7% and asymptomatic 0%. On 15th day, the percentages are, sever 0%, Moderate 5%, mild 65%, and asymptomatic 30%. On 30th day, the percentages are, sever 0%, Moderate 0%, mild 35% and asymptomatic 65% and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 15%, and asymptomatic 85%. Calculating Chisquare Value of Visit 1 v/s Visit 4, 92.1 with df 3 than

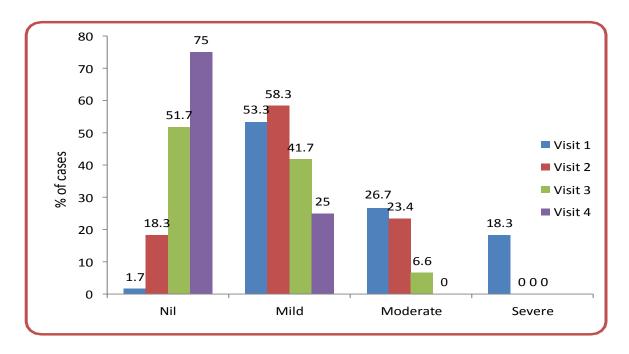
the p-Value is 0.001 which is significant. According to grades of nasal obstruction, significant changes are found from zero day to 45th day. 51 patients out of 60 have got complete relief. While 9 patients have remained with little symptoms. Chi-square value is 92.1 with df 3 and P< 0.05 is considered to be statically significant. Hence the drug is effective in nasal obstruction. It shows that this *Safoof* is having *mohallil-e-auram* (anti-inflammatory) property.



Effect on Sneezing: 0 day, the percentages are, severe 18.3%, Moderate 26.7%, mild 53.3% and asymptomatic 1.7%. On 15th day, the percentages are, sever 0%, Moderate 23.4%, mild 58.3%, and asymptomatic 18.3%. On 30th day, the percentages are, sever 0%, Moderate 6.6%, mild 41.7% and asymptomatic 51.7 and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 25%, and asymptomatic 75%. Calculating Chi-square

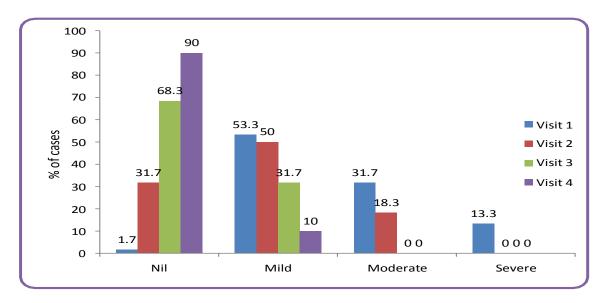
Value of Visit 1 v/s Visit 4 is 75.2 with df 3 than the p Value is 0.001 which is significant. According to grades of sneezing, significant change is found from zero day to 40th day. 45 patients out of 60 have got complete relief. While 15 patients have remained with little symptoms. Chi square value is 75.2 with df 3 and P< 0.05 is considered to be statically significant. Hence the drug is effective in nasal discharge.

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Effect on Malaise: 0 day, the percentages are, severe 13.3%, Moderate 31.7%, mild 53.3% and asymptomatic 1.7%. On 15th day, the percentages are, sever 0%, Moderate 18.3%, mild 50%, and asymptomatic 31.7%. On 30th day, the percentages are, sever 0%, Moderate 0%, mild 31.7% and asymptomatic 68.3 and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 10%, and asymptomatic 90%. Calculating Chi-square Value of

Visit 1 v/s Visit 4 is 95.9 with df 3 than the p-Value is 0.001 which is significant. According to grades of Malaise, significant changes are found from zero day to 40th day. 54 patients out of 60 have got complete relief. While 6 patients have remained with little symptoms. Chi-square value is 95.9 with df 3 and P< 0.05 is considered to be statically significant. Hence the drug is effective in nasal discharge.



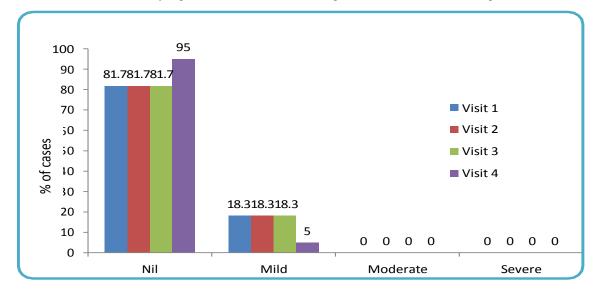
Effect on Hypertrophied Nasal Mucosa: 0 day, the percentages are, severe 0%, Moderate 0%, mild 18.3% and asymptomatic 81.7%. On 15th day, the percentages are, sever 0%, Moderate 0%, mild 18.3%, and asymptomatic 81.7%. On 30th day, the percentages are, sever 0%, Moderate 0%, mild 18.3% and asymptomatic 81.7 and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 5%, and asymptomatic 95%.

Calculating Chi-square Value of Visit 1 v/s Visit 4 is 5.2 with df 1 than the p-Value is 0.043 which is significant. According to grades of HNM, significant change is found from zero day to 40th day. Out of 60 patients only 11 patients have a complain of HNM in mild stage, after completion of 45 days 7 patients out of 11 has got complete relief. While 3 patients have remained with little symptoms. Chi-square value is 5.2 with df 1 and P<

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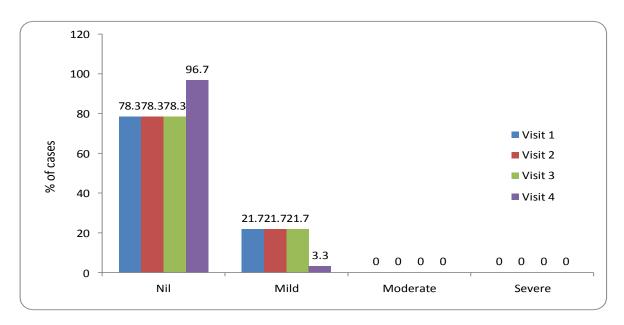
0.05 is considered to be statically significant. Hence the

drug is effective in nasal discharge.



Effect on Deviated Nasal Septum: 0 day, the percentages are severe 0%, Moderate 0%, mild 21.7% and asymptomatic 78.3%. On 15th day, the percentages are, sever 0%, Moderate 0%, mild 21.7%, and asymptomatic 78.3%. On 30th day, the percentages are, sever 0%, Moderate 0%, mild 21.7% and asymptomatic 78.3 and on 45th day, the percentages are, sever 0%, Moderate 0%, mild 3.3%, and asymptomatic 96.7%. Calculating Chi-square Value of Visit 1 v/s Visit 4 is 9.2

with df 1 than the p-Value is 0.004 which is significant. According to grades of DNS, significant changes are found from zero day to 40th day. Out of 60 patients only 13 patients have a complain of DNS in mild stage, after completion of 45 days 11 patients out of 13 has got complete relief. While 2 patients have remained with little symptoms. Chi-square value is 9.2 with df 1 and P< 0.05 is considered to be statically significant. Hence the drug is effective in nasal discharge.



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Conflict of Interest

Nil.

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