Management of Chronic Rhinosinusitis with Habb-e-Shifa and Steam Inhalation

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Abstract

Present study was designed to determine the efficacy of *Habb-e-Shifa* and a combined therapy of *Habb-e-Shifa* and steam inhalation in two groups of 30 patients each of Chronic Rhinosinusitis. Patients in Group I were treated with *Habb-e-Shifa* (2 tablets) orally twice daily for 14 days, whereas those in Group II were treated with steam inhalation along with *Habb-e-Shifa* (2 tablets) twice daily for 14 days. The main five symptoms of Chronic Rhinosinusitis.viz. rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing were assessed using VAS sheet. Baseline scores of symptoms were compared with final scores and analyzed statistically using Student's't' test.

In both the groups the symptoms were found to be improved significantly, however the degree of effect in respect of Group II was higher as compared to Group I. The study thus demonstrated that *Habb-e-Shifa* is an effective drug to manage the cases of Chronic Rhinosinusitis but the maximum therapeutic effect is achieved when it is combined with steam inhalation.

Keywords: Chronic Rhinosinusitis, *Habb-e-Shifa*, Unani Medicine, Steam inhalation, Anti-inflammatory

Introduction

Nasal mucosa remains in continuous exposure to the environment, facing air of different temperatures, dust, pathogens, allergens and many foreign particles. This exposure makes it vulnerable to be diseased, causing different inflammatory conditions affecting nasal as well as sinus mucosa. Upper respiratory tract infections, rhinitis, sinusitis and rhinosinusitis are among the most frequent reasons to see a medical practitioner. Chronic Rhinosinusitis is an inflammatory disease of the mucosa of the nasal cavity and paranasal sinuses with symptoms lasting longer than 12 weeks or occurring at least 6 episodes per year (Benninger *et al.,* 2003).

The main clinical features of Chronic Rhinosinusitis are recurrent rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing. The diagnosis is typically clinical by identifying signs and symptoms that can be seen by anterior rhinoscopy. During acute exacerbation, on rhinoscopy or on simple nasal examination the inflamed nasal mucosa and nasal discharge, is seen in almost all patients.

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Chronic Rhinosinusitis, rhinitis and sinusitis are being managed with modern as well as Unani medicines with varying degree of success. The basic principles of management of rhinosinusitis and related conditions are to reduce the inflammation, facilitate the drainage both during and after treatment, to prevent recurrence and treat any infection, if present. Pharmacological measures include the use of anti-inflammatory analgesic, antipyretic, antihistaminic, decongestant, anticholinergic drugs and also the corticosteroids (systemic/topical) and sometimes antibiotics, while adjunctive (non-pharmacologic) measures include steam inhalations, saline irrigation, and use of hot/dry air to promote drainage through the sinus ostia and ciliary function. (Druce, 1990; Meltzer, 1995).

In Unani system of Medicine drugs having *muhallil-e-auram, musakkin, mujaffif-e-ratubat, habis wa qabiz and dafe ratubaat-e-fasida* etc. effects are commonly used for the management of Chronic Rhinosinusitis and other similar clinical conditions.

Habb-e-Shifa (Table 1) is one such pharmacopoeal preparation that possesses befitting medicinal values as required to treat the inflammatory condition of nasal and sinus mucosa. It is useful in most of the rhinorrhoea e.g. *Nazla* (Common cold)*, Nazla Shadeed* (Severe Rhinitis) and in *Nazla Balghami* (Khan, 1987; Khan, 2011). It also has analgesic effect and used in headache (Kabeeruddin, 1977). Unani Physicians are also using *Habb-e-Shifa* in different inflammatory conditions of nose and para-nasal sinuses, successfully. In some of the studies conducted in recent years it has been demonstrated to possess significant analgesic, anti inflammatory and other related effects (Tajuddin *et al.,* 2007; Haq, et al. 2009). Therefore the present study was planned to evaluate the efficacy of *Habb-e-Shifa* in patients of Chronic Rhinosinusitis. However, since inhalation is one of the most advised and commonly practiced adjunctive measures to manage upper respiratory disorders therefore the effect of *Habb-e-Shifa* was also studied in a separate group of patients who were treated with steam inhalation along with oral administration of *Habb-e-Shifa* so as to determine the differential effect of the two.

Table 1 : Ingredients of *Habb-e-Shifa*

S. No.	Unani name	Scientific name	Parts used	Weight (gm)
1.	*Jauz-e-Masil*	*Datura stramonium* Linn.	Seed	300
2.	*Revand Chini*	*Rheum emodi* Wall. ex Meissn.	Root	200
3.	*Zanjabeel*	*Zingiber officinale* Rosc.	Rhizome	100
4.	*Samagh-e-Arabi*	*Acacia arabica* Willd.	Gum	100

Material and Method

This study was conducted at Department of Ilaj-bit-Tadbeer and Department of Moalejat, Ajmal Khan Tibbiya College, AMU, Aligarh on 60 patients, divided into two groups, of 30 patients each. The patients were taken up from the outpatient department of A.K. Tibbiya College Hospital and randomly allocated to both the groups. Patients in Group I were treated with *Habb-e-Shifa* (2 tablets) orally twice a day for 14 days, whereas those in Group II received *Habb-e-Shifa* (2 tablets) and Steam inhalation twice daily for the same period.

Patients were taught to mark the severity of the main five symptoms of Chronic Rhinosinusitis on VAS sheet, where 0 stands for no symptom and 3 for maximum severity. VAS sheet marking was done at the commencement of the treatment, at 7^{th} day and at the end of the treatment i.e. at 14^{th} day and the scores for all the five symptoms were noted. For each group baseline scores and final scores were analyzed statistically by applying Student's paired't' test to assess the efficacy of *Habb-e-Shifa* alone and in adjunct of steam inhalation on the signs & symptoms and on the overall clinical condition of Chronic Rhinosinusitis.

Inclusion Criteria

- Age between 15 years to 60 years of both sexes.
- Having typical symptoms of Chronic Rhinosinusitis viz. rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing for more than 12 weeks.

Exclusion Criteria

- Patients who received medication for Chronic Rhinosinusitis in last 2-3 weeks
- Use of systemic corticosteroid within 2 months or nasal corticosteroid within 2 weeks
- Gross Nasal Structure deformity, Large nasal polyp or Hypertrophic rhinitis
- Other active respiratory disorder
- Active medical disorders like Systemic infection, Haematological, Renal, Hepatic, Cardiovascular, Gastric and Metabolic disorders etc.
- Pregnant and Lactating women

Observations and Results

Effect of the test drugs was observed in each patient on the five major signs and symptoms of Chronic Rhinosinusitis and the findings have been presented in tabular form as follows:

Table 2 : Rhinorrhoea

Group 1		Group 2	
Baseline Score	Final Score	Baseline Score	Final Score
2.27 ± 0.69	1.10 ± 0.66	2.03 ± 0.61	0.80 ± 0.55
t = 16.86	p<0.001	t = 15.70	p<0.001

Table 3 : Nasal congestion

Group 1		Group 2	
Baseline Score	Final Score	Baseline Score	Final Score
2.37 ± 0.49	1.17 ± 0.46	2.43 ± 0.50	0.87 ± 0.35
t = 16.15	p<0.001	t = 17.03	p<0.001

Table 4 : Frontal headache

Group 1		Group 2	
Baseline Score	Final Score	Baseline Score	Final Score
2.27 ± 0.52	1.10 ± 0.55	2.33 ± 0.55	1.00 ± 0.37
t = 13.86	p<0.001	t = 13.56	p<0.001

Table 5 : Nasal itching

Group 1		Group 2	
Baseline Score	Final Score	Baseline Score	Final Score
1.20 ± 0.76	0.90 ± 0.66	1.23 ± 0.63	0.70 ± 0.54
t = 3.53	p>0.001	t = 5.76	p<0.001

Table 6 : Frequent sneezing

Group 1		Group 2	
Baseline Score	Final Score	Baseline Score	Final Score
1.17 ± 0.98	0.70 ± 0.65	1.53 ± 0.68	0.57 ± 0.50
t = 4.47	p<0.001	t = 9.52	p<0.001

Table 7 : Statistical analysis for Cumulative score

Group 1		Group 2	
Baseline Score	Final Score	Baseline Score	Final Score
9.37 ± 1.79	4.97 ± 1.40	9.57 ± 1.59	3.93 ± 1.11
t = 19.75	p<0.001	t = 28.94	p<0.001

Discussion

The study demonstrated that both *Habb-e-Shifa* alone and in combination with steam inhalation produced significant effect in the patients of Chronic Rhinosinusitis as all five major symptoms i.e. rhinorrhoea, nasal congestion, frontal headache, nasal itching and frequent sneezing and the overall clinical condition was found improved significantly (Table 2-7). However, the effect produced by the combined therapy (*Habb-e-Shifa* + steam inhalation) was comparatively better than *Habb-e-Shifa* alone, as is evident from the difference of't' values.

As per description contained in Unani literature, the temperament of *Jauz-e-masil* (*Datura stramonium* Linn.) is *barid yabis* (cold & dry) in 4° and is described to have *Musakkin, Mujaffif–e-ratubat Ghareeba and Habis wa Qabiz* effects (Ghani, ynm; Khan, 2013); these effects possibly reduced rhinorrhoea and headache, while *Dafe ratubaat* effect of *Zanjabeel* (*Zingiber officinale* Rosc.) and *Mujaffif-e-ratubat* effect of *Revand chini* (*Rheum emodi* Wall. ex Meissn.) may have complemented the effect of *Jauz-e-masil* in reducing the rhinorrhoea (Ghani, ynm; Khan, 2013; Hakeem, 2002). Some of the recent scientific data suggested that *Jauz-e-masil* (*Datura stramonium* Linn.) has anti-cholinergic, anti-muscarinic, analgesic, anodyne and anti-inflammatory effects (Das *et al.,* 2012; Devi *et al.,* 2011; Soni *et al.,* 2012; Chopra *et al.,* 1956), therefore, it is likely that these attributes of Jauz-*e-masil* may have played a role in reducing the inflammation and oedema of nasal/sinus mucosa and secretion from it**.** Medicinal properties of *Jauz-e-masil* have been attributed mainly to the presence of atropine and scopolamine. *Zanjabeel* (*Zingiber officinale* Rosc.) has [6]-gingerol, an active chemical constituent (Young *et al.*, 2005) that has anti-inflammatory, analgesic and oedema reducing effects (Ojewole, 2006; Raji *et al.*, 2002; Penna *et al.*, 2003), therefore, on account of having these medicinal effects *Zanjabeel* is also likely to reduce the rhinorrhoea, nasal congestion and headache. However, since all the drugs of *Habb-e-Shifa* were given in combination (pills form) therefore it is more likely that the total response of *Habb-e-Shifa* has induced the desirable effect.

Steam by virtue of having local anti-inflammatory/analgesic and soothing effects and also acting as muco-diluent and muco-evacuant effect (Ophir, 1987; Tyrrell, 1989; Georgitis, 1994; Evans, 1998; Lance *et al.*, 2000), is supposed to have increased the nasal patency and reduced the secretion to alleviate the symptoms. Thus the collective response produced by *Habb-e-Shifa* and steam inhalation was more significant as compared to the effect of *Habb-e-Shifa* alone.

Nasal discharge initiates sneezing through nasal itching that arise due to macerated and hypersensitive/inflamed nasal mucosa. The possible anti-cholinergic/anti-muscarinic and anti-inflammatory effects of complete regimen (*Habb-e-Shifa* and Steam Inhalation) might have relieved rhinorrhoea, nasal congestion and frontal headache on one hand and subsided nasal itching and frequent sneezing on the other. The preclinical and clinical studies conducted by Tajuddin *et al.* (2007) and Haq *et al.* (2009), respectively on *Habb-e-Shifa* also support the result of our study.

During the study it was noted that 8 out of total 60 patients reported dryness of mouth and 2 patients complained of mild blurring of vision, but these unwanted effects did not create any major hindrance in routine practices of the patients, as no dropout was recorded. These unwanted effects of *Habb-e-Shifa* may be due to anti-cholinergic and anti-muscarinic effect of *Jauz-e-masil* which is the chief ingredient of *Habb-e-Shifa.* But the findings pointing towards the side effect warrant that toxicity study of this drug should be conducted on relatively larger number of subjects to prepare a safety/ toxicity profile.

In the light of the findings it can be conclude that *Habb-e-Shifa* is an effective Unani formulation, useful in the management Chronic Rhinosinusitis, however it produces optimal effect when the patient is treated simultaneously with steam inhalation.

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