

<https://doi.org/10.48047/AFJBS.6.4.2024.1354-1362>



African Journal of Biological Sciences

Journal homepage: <http://www.afjbs.com>



Research Paper

Open Access

## Clinical Validation to evaluate the safety and efficacy of Unani Pharmacopeial formulation *Habb-e-Banafsha* in the Management of *Dīq al-Nafas* (Bronchial Asthma)

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Volume 6, Issue 4, April 2024

Received: 15 Mar 2024

Accepted: 05 April 2024

Published: 25 April 2024

[doi: 10.48047/AFJBS.6.4.2024.1354-1362](https://doi.org/10.48047/AFJBS.6.4.2024.1354-1362)

### Abstract

**Background:** Asthma is defined as a heterogeneous disease, usually characterized by inflammation, bronchial hyper-responsiveness and chronic remodelling of the airways.

**Aim:** The purpose of the study is to validate the efficacy of a compound formulation *Habb-e-Banafsha* in the management of *Dīq al-Nafas* (Bronchial Asthma) for a period of four weeks.

**Method:** Multi-centric open label clinical study was strategized; 110 patients completed the 4 weeks protocol therapy. 2 tablets of *Habb-e-Banafsha* was given thrice daily for a period of four weeks.

**Result:** While 48.18% of patients were only partially controlled, 24.55% of patients experienced complete relief. Patients of *Balghamī* temperament, ages 40 to 50, exhibited the highest level of response. There were no negative consequences noted during the study.

**Conclusion:** *Habb-e-Banafsha* is safe and effective in the management of *Dīq al-Nafas* (D-4)

**Keyword:** *Dīq al-Nafas*, Asthma, *Banafsha*, Unani, *Rabw*, *Buhr*

### Introduction

Asthma is a chronic inflammatory disease of the airways due to bronchial hyper-responsiveness and the tendency of airways to unduly constrict in response to stimuli. The cardinal symptoms comprises of repeated episodes of wheezing, breathlessness, chest

tightness, and night time or early morning coughing.<sup>1,2</sup> According to Global Initiative for Asthma (GINA) 5-10% of population is asthmatic affecting 339 million people worldwide and caused 455000 deaths.<sup>3,4</sup> Approximately 20% of asthmatics currently smoke, a prevalence comparable to that found in the general population.<sup>5,6</sup> In classical literature asthma is defined as exudation of *Balgham Ghayr Tabī'ī* from *Kasbatul-Riyah* and *Urooq-e-Khashina* result in obstruction of airways.<sup>7</sup> *Sahib Kamil 'Ali Ibn 'Abbās Majūsī* described congestion of arteries of lungs as *Buhr* (cardiac Asthma) and congestion of bronchioles as *Rabw* which is equivalent to bronchial asthma.<sup>8</sup> According to *Shaykh al-Ra'īs Ibn Sīnā*, the patient is breathing like a tired person, the respiration is rapid (*Sarī*), shallow (*Saghīr*) and frequent (*Mutawātir*) and this is due to accumulation of abnormally excessive *Ghalīz* (thick), *Lazij* (vitreous consistency) humour.<sup>9</sup> *Ismā'īl Jurjānī* in his book *Dhakhīra Khawārizm Shāhī* defined that the patient is incapable to gasp even while resting also its difficult for elderly to heat up the humour (*Mawād Illat*) collected in their chest.<sup>10</sup> Principal treatment of *Dīq al-Nafas* D-4 includes *muhallilat* (resolvent), *Mufatti -i- 'Urūq Khashna* (Bronchodilator), *Mulatṭif* (demulcent), *Munaffith* (expectorant), *Dāfi -i-Tashannuj-i-Shu'ab* (anti-bronchospasmodic) and *Dāfi -i-Hassāsiyat* (anti-histamine). Unani physicians have been practicing effective treatment for *Dīq al-Nafas*. There are many single and compound formulations used in its management. One such well-known formulation is *Habb-e-Banafsha*. Thus, the study is proposed to validate the safety and efficacy of *Habb-e-Banafsha* in the management of *Dīq al-Nafas*.

## Methodology

**Study Design:** The study was prospective, an open-labelled, multi-centric single arm clinical study. Although the study was multi-centric, this study represents the result of one of the peripheral centre i.e. Clinical Research Unit, Meerut.

**Ethical consideration:** Ethics Committee approved the protocol on 22/11/2021. The study is registered with Clinical Trial Registry of India (CTRI/2021/05/033781) and was implemented in accordance with provisions of the Declaration of Helsinki and Good Clinical Practice (GCP) guidelines.

**Study participants:** Every patient was assessed to determine their eligibility for the trial and informed consent was acquired. A total of 126 patients were enrolled.

**Inclusion criteria:** The patients aged between 18-60 years meeting the Rome III diagnostic criteria for post prandial distress syndrome were screened.

**Exclusion criteria:** Patient with alarming symptoms like weight loss, severe anaemia, hematemesis, melena or any abdominal mass or uncontrolled systemic disease were not included. Pregnant and lactating mothers were also excluded.

**Intervention:** Study medicine- *Habb-e-Banafsha* is a classical poly-herbal formulation and was procured from NRIUMSD, Hyderabad. 2 tablets of *Habb-e-Banafsha* thrice daily was given orally for 4 weeks, the patients were clinically examined on 0-day, 14<sup>th</sup> day and 28<sup>th</sup> day.

**Study Procedure:** The study was conducted for a period of 3 years approximately from 18/08/2020 to 03/03/2022 at Clinical Research Unit, Cantonment General Hospital, Meerut, Uttar Pradesh. 126 patients were screened and those fulfilling the inclusion criteria were enrolled; 16 cases were dropped out and rest 110 patients completed the research study.

**Outcomes:** For evaluating efficacy, Asthma Controlled Questionnaire was used. For assessing safety, all patients were questioned for adverse effects. Systemic examination and laboratory parameters such as CBC with ESR, Liver and Kidney function test, and Urine routine microscopic were done before and after the treatment.

**Statistical Analysis:** The data analysis was done by statistician using IBM SPSS Statistics 2.0 (1989-2011). Student t-test, Mann-Whitney test and Chi-square/ Fisher Exact were used to find the significance of study parameters on continuous scale and categorical scale respectively.

### Observation & Results:

**Table 1. Demographic details of the patients completed the study**

Age Group in years	Sex		Total
	Male	Female	
18-28 year	1	15	16 (14.5%)
29-39 year	8	19	27 (25.5%)
40-50 year	12	24	36 (32.7%)

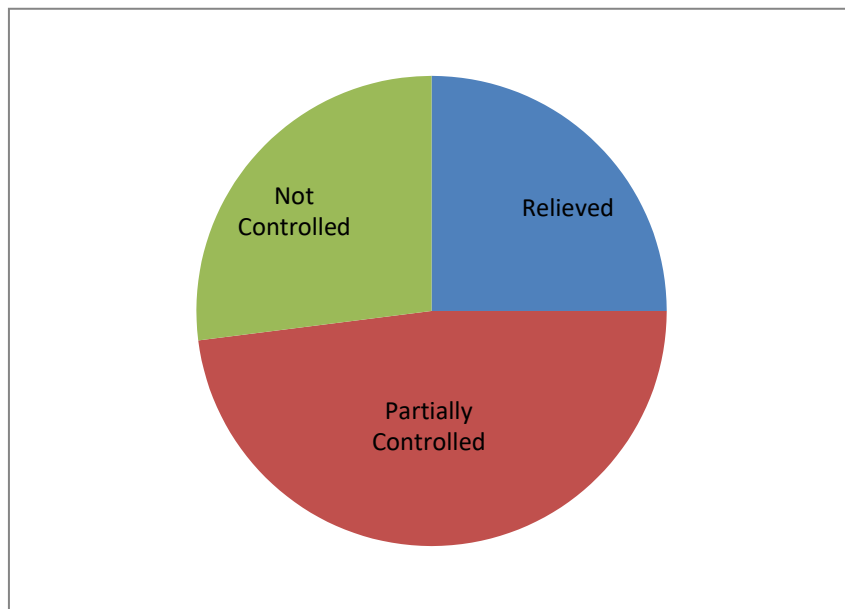
51-65 year	15	16	31(28.2%)
<b>Total</b>	<b>36</b>	<b>74</b>	<b>110</b>
<b>Temperament</b>			
Damvi (Sanguine)	0	0	0
Balghami (Phlegmatic)	26	42	68 (61.8%)
Safravi (Bilious)	9	32	41 (37.3%)
Saudavi (Melancholic)	1	0	1 (0.9%)
<b>Total</b>	<b>36</b>	<b>74</b>	<b>110</b>
<b>Income group</b>			
Lower	22	45	67 (60.9%)
Middle	14	29	43 (39.1%)
Higher	0	0	0
<b>Total</b>	<b>36</b>	<b>74</b>	<b>110</b>
<b>Marital status</b>			
<b>Married</b>	35	64	99 (90%)
<b>Unmarried</b>	01	10	11 (10%)
<b>Total</b>	<b>36</b>	<b>74</b>	<b>110</b>
<b>Family history of Bronchial Asthma</b>			
<b>Yes</b>	4	11	15 (13.6%)
<b>No</b>	32	63	95 (86.4%)
<b>Total</b>	<b>36</b>	<b>74</b>	<b>110</b>
<b>History of smoking</b>			
<b>Yes</b>	07	0	07 (6.4%)
<b>No</b>	29	74	103 (93.6%)
<b>Total</b>	<b>36</b>	<b>74</b>	<b>110</b>

Table 2. Safety assessment of *Habb-e-Banafsha* in *Dīq al-Nafas* (Bronchial Asthma)

	Before Treatment	After Treatment	P value
<b>Hemogram</b>	11.07 ± 0.12	11.32 ± 0.13	< 0.001
<b>TLC</b>	9124 ± 178	8905 ± 101	0.13
<b>Neutrophils</b>	55.58 ± 0.52	56.01 ± 0.53	0.463
<b>Lymphocytes</b>	35.41 ± 0.49	35.86 ± 0.53	0.45
<b>Eosinophil</b>	5.72 ± 0.18	5.17 ± 0.12	0.003
<b>Monocytes</b>	3.33 ± 0.12	3.23 ± 0.12	0.466
<b>ESR</b>	17.8 ± 1.12	12.36 ± 0.57	< 0.001
<b>Serum Bilirubin</b>	0.87 ± 0.02	0.81 ± 0.01	0.155
<b>SGOT</b>	28.76 ± 0.74	27.78 ± 0.64	0.021
<b>SGPT</b>	32.55 ± 1.41	30.20 ± 0.90	0.002
<b>ALP</b>	100.59 ± 0.66	95.42 ± 0.60	< 0.001
<b>Serum Creatinine</b>	0.92 ± 0.02	1.01 ± 0.21	0.395
<b>Serum Urea</b>	23.72 ± 0.37	26.76 ± 1.42	0.036

**Table 3. Response of *Habb-e-Banafsha* in *Dīq al-Nafas* (Bronchial Asthma)**

Response	No. of Patients
Relieved	27 (24.55%)
Partially Controlled	53 (48.18%)
Not Controlled	30 (27.27%)



**Figure 1. Response of *Habb-e-Banafsha* in *Dīq al-Nafas***

**Table 4. Effect of *Habb-e-Banafsha* on symptoms of *Dīq al-Nafas***

Cough	Before Treatment	After Treatment
Absent	0	65 (59.09%)
Mild	1 (0.9%)	37 (33.63%)
Moderate	19 (17.3%)	07 (6.36%)
Severe	90 (81.8%)	1 (0.9%)
<b>ACQ</b>		
Well controlled	06 (5.5%)	25 (22.7%)
Moderately controlled	34 (30.9%)	60 (54.54%)
No control	70 (63.63%)	25 (22.72%)
<b>Absolute Eosinophil count</b>	257.74 ± 9.87	232 ± 7.49
<b>FEV1</b>		
Normal	11 (10%)	25 (22.72%)
Mild obstruction	39 (35.5%)	49 (44.54%)
Moderate obstruction	59 (53.6%)	36 (32.72%)
Severe obstruction	1 (0.9%)	0
<b>FEV1/FVC</b>		
Normal	13 (11.82%)	28 (25.45%)
Mild airflow limitation	37 (33.64%)	46 (41.82%)
Moderate airflow limitation	60 (54.54%)	36 (32.73%)

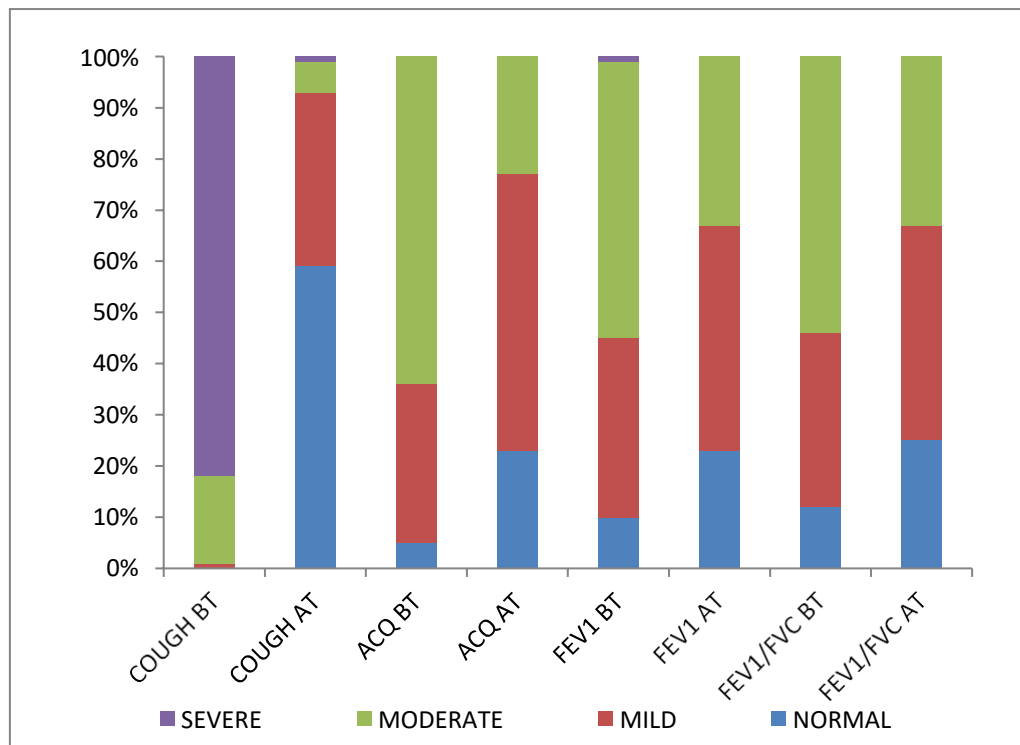


Fig-2 Effect of *Habb-e-Banafsha* on symptoms of *Dīq al-Nafas*

Discussion

### Demographic distribution

Highest incidence of *Dīq al-Nafas* D-4 (Bronchial Asthma) i.e. 32.7% (n-36) was observed in the age group 40-50 years followed by patients belonging to age group 51-65 years which are 28.2 % (n-31). As far as gender distribution is concerned majority of the patients were female 67.3% (n-74) followed by male 32.7 % (n-36). When assessed the socioeconomic status of the patients, as per the Kuppuswamy scale, maximum number of patients in the study belongs to Lower Income Group i.e. 60.9% (n-67), while 39.1% of the patients belong to middle income group and this findings may be due to the catchment areas of the hospital, where majority of the families belongs to lower income group. While interrogate about marital status majority of the patients 90% (n-99) were married followed by 10% unmarried patients. Family history and personal history of the patients were also assessed during the study. It was revealed that 86.4% (n-95) were not having family history of bronchial asthma while 93.6% (n-103) were not having history of smoking. *Mizaj* of the patient was determined as per the *Ajnās 'Ashra* and 61.1% (n-77) were phlegmatic (*Balghamī*) and 38.89% (n-49) were bilious (*Safrāvī*) (Table 1).

### Safety assessment

Throughout the course of the treatment, all haematological and biochemical parameters stayed normal, leading to the conclusion that *Habb-e-Banafsha* is safe and hasn't altered any safety parameters. No adverse effect was complained during the treatment therapy by any patient at any visit of follow-up. The statistical evaluation revealed that the p-value for the parameters assessed under the Hemogram, Liver Function Test, and Kidney Function Test was not significant (Table 2).

### Efficacy Assessment

Out of 110 Patients, 24.55% (n- 27) were relieved and 48.18% (n-53) were partially controlled and 27.27% (n-30) had no effect at all (Table 3 Figure 2). 81.8% (n-90) patients had a severe cough at baseline; following therapy, 59.09% (n-65) patients had no cough, and 33.63% (n-37) had just a mild cough. According to Asthma Control Questionnaire, it has been observed that there were 63.63% (n-70) patients with no asthma control at baseline and after the treatment there were 22.7% (n-25) and 54.54% (n-60) patients with well controlled and moderately controlled asthma respectively. These findings suggest the efficacy of Unani drug *Habb e Banafsha* in the management of *Dīq al-Nafas* (Bronchial Asthma). While

assessing the Absolute Eosinophil count, it was observed that no significant change was observed in AEC after the treatment therapy. When assessed FEV1, out of 110 patients, 53.6% (n-59) and 35.5% (n-39) had complaint about moderate to mild obstruction respectively while after the treatment there were 22.72% (25) with no obstruction, 44.54% (n-49) with mild obstruction and 32.72% (n-36) had moderate obstruction. After therapy, 25.45% (n-28) had no airflow limitation, 41.82% (n-46) had mild airflow limitation, and 32.73% (n-36) had moderate airflow limitation. At baseline, 54.54% (n-60) patients had moderate airflow limitation, and 33.64% (37) had light airflow limitation and after the treatment 25.45% (n-28) had no airflow limitation 41.82% (n-46) had mild and 32.73% (n-36) had moderate airflow limitation (Table 4 Figure 4).

### Conclusion

The aim to validate scientifically the efficacy of *Habb-e-Banafsha* in the management of *Dīq al-Nafas* (Bronchial Asthma) was successful. The result of the study conducted at Clinical Research Unit Meerut, concludes that *Habb-e-Banafsha* can be used as an adjuvant in the management of *Dīq al-Nafas* (Bronchial Asthma). More clinical studies are required to establish the efficacy as well mechanism of action of *Habb-e-Banafsha*.

### Acknowledgement

We are thankful to CCRUM, Ministry of AYUSH, for well-equipped project and all type of financial and medicinal help.

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