Study of *Warme Shoab Muzmin* (Chronic Bronchitis) with therapeutic evaluation of a Unani formulation

Shah A H *, Haji A, Siddiqui M A, Ansari A N & Sofi G
National Institute of Unani Medicine, Bangalore, 560091
E-mail: altafnium@gmail.com

Received 11.05.10; revised 31.01.11

The study was conducted as a single blind, randomized and standard controlled trial. Forty patients of Warme Shoab Muzmin were selected and randomly assigned to control and test groups; comprising 20 patients in each group. Test formulation consisting Aslussooz (*Glycyrrhiza glabra*), Parsiyaoshan (*Adiantum capillus veresis*), Zufayabis (*Hyssopus officinalis*) and Sapistan (*Cordia dichotoma*) was given to the test group in the dose of 20 gm/day in decoction form for 45 days. The standard group received Ambroxol as a standard drug in the dose of 75 mg in tablet form once a day orally for 45 days. All the patients were assessed for subjective and objective parameters. The results were analyzed statistically using Mann-Whitney test ‘U’, Wilcoxon matched pairs signed rank test and student’s ‘t’ test. The test drug exhibited statistically significant improvement in cough (p<0.004), sputum production (p<0.001), and breathlessness (p<0.0146) in subjective parameters in comparison to control group. A significant improvement was also observed in wheezes (p<0.004), chest X-Ray findings (p<0.0477), and spirometric measures consisting of FEV₁ % predicted (p<0.01), FEV₁/FVC % (p<0.019), and PEF (p<0.03).

**Keywords:** Warme Shoab Muzmin, Chronic bronchitis, Unani medicine, Spirometry

**IPC Int. CL**: A01D 11/00, A01D 11/07, A01D 11/08, A01D 11/18

Chronic obstructive pulmonary disease (COPD) which includes chronic bronchitis is a common cause of morbidity and mortality worldwide. It is of major concern for society as the progressive disease causes increasing disability for the patients and a burden for society. It is the fourth leading cause of death worldwide and is estimated to be the third leading cause of death by 2020¹. Chronic bronchitis affects 10-25% of adult population². In India, its prevalence is 5% among men and 3.2% in women adults of 30 yrs of age and above³. Chronic bronchitis is a clinical condition characterized by the presence of chronic cough and sputum expectoration occurring on most days for at least 3 months of the year and for at least 2 consecutive years when other respiratory or cardiac causes for the chronic productive cough are excluded. The disease is caused by an interaction between noxious inhaled agents (e.g. cigarette smoke, industrial pollutants, and other environmental pollutants) and host factors (e.g. genetic and respiratory infections) that result in chronic inflammation in the walls and lumen of the airways⁴,⁵.

*Warme Shoab Muzmin* is literal translation of chronic bronchitis rendered by contemporary Unani physicians. The therapeutic management as offered by modern medicine, consisting of the use of antibiotics, bronchodilators and steroids, is able to provide only temporary relief. Besides, the group of drugs mentioned above entails elements of toxicity and numerous side effects and the chronicity of the disease further limits the use of drugs over a long period of time. In the wake of unconvincing scenario, the Unani medicine axiomatically comes to the fore as the *Warme Shoab Muzmin* has successfully been treated since ancient time without considerable obnoxious side effects on the body. Unani medicine

---

¹Corresponding author
swears by such drugs which have been used in Warme Shoab Mazmin (chronic bronchitis) effectively and stood the test of the time. From a pool of efficacious drugs for this disease, a pharmacopeial compound formulation comprising drugs namely Aslussoos (*Glycyrrhiza glabra*), 10.5 gm), Parsiyaooshan (*Adiantum capillus veresis*), 3.5 gm), Zafa yabis (*Hyssopus officinalis*), 3.5 gm) and Sapistan (*Cordia dichotoma*), 10 pieces) has been taken from the reputed pharmacopeia ‘Quarabadine Azam’, for the trial purpose.

The efficacy of this formulation has been evaluated on the basis of standard parameters. The efficacy of the test drug was compared with the standard drug Ambroxol. The evaluation of the efficacy was based on subjective parameters like cough, sputum production and breathlessness and objective parameters as wheezes, crepitations, Chest X-ray findings and Spirometric measures following the protocols as advised in NIOSH spirometry training guide. The outcome was analyzed and compared using appropriate statistical tests.

**Material and methods**

A single blind, randomized, standard controlled study, approved by the NIUM ethics committee, was carried out on patients of Warme Shoab Mazmin attending OPD/IPD of National Institute of Unani Medicine, hospital, Bangalore from July 2008 to February 2009.

**Inclusion criteria:** Patients fulfilling the following criteria were included:

1. Patients of chronic bronchitis
2. Patients of either sex
3. Patients above 30 yrs of age.

**Exclusion criteria:** Patients having following diseases were excluded:

1. Emphysema
2. Bronchiectasis
3. Bronchial asthma
4. Tuberculosis
5. Pneumonia
6. Lung carcinoma
7. Acute bronchitis.
8. Obliterative bronchiolitis
9. Diffuse panbronchiolitis
10. Acute respiratory tract infection
11. Patients below 30 yrs of age
12. Pregnant women
13. Hypertension
14. CHF
15. Diabetes mellitus.

Patients were selected on the basis of clinical diagnosis. Any patient, above 30 yrs of age, giving history of chronic cough for 3 months during each of the 2 successive years, was selected from Moalajat OPD/IPD and evaluated for the consideration as a research subject. In the process of selection, spirometry was done. If the FEV/FVC was found <80% and referred investigations were found normal; the patient was diagnosed as a case of Warme Shoab Mazmin (chronic bronchitis). These diagnosed patients, if fulfilled all the terms of inclusion criteria, were selected for the study and allocated into control and test group by randomization. Written informed consent was sought from every patient before inclusion in the study.

Following investigations were done in every case aiming at 3 important objectives.

(a) To exclude the patients other than Warme Shoab Mazmin (chronic bronchitis) as a part of exclusion criteria; (b) Assess the objective parameters in various treatment groups, and (c) To establish the safety of the test drug.

Hb%, TLC, DLC, AEC, ESR, Fasting blood sugar, Post prandial blood sugar, SGOT, SGPT, blood urea, serum creatinine, X-Ray Chest PA view, Spirometry and ECG. All investigations were done before starting and after stopping the treatment.

Forty patients were randomly allocated by using lottery method into two groups comprising 20 patients in each of control (Group A) and test (Group B) groups, respectively. The treatment period in both test and control groups was fixed as 45 days. Twenty gm of test formulation in decoction form was given to Group B (test group) patients once in morning before taking breakfast. Ambroxol, in the dosage of 75 mg per day in tablet form was administered in 20 patients of Group A (Control Group). Forty five days study was divided into 4 visits of follow up which were made at an interval of 15 days. At every visit, the patients were asked about the improvement or worsening in their symptoms and subjected to examination to assess clinical findings.

The assessment of the efficacy in the test and control groups was based on two types of parameters:
(A) Subjective parameters, and (B) Objective parameters

Subjective parameters included cough with sputum, wheezing and breathlessness, while assessment of objective parameters included findings in (X-Ray chest PA view) and spirometry measurements of the patients suffering from Warme Shoab Muzmin.

As these parameters differ in severity from patient to patient, an arbitrary grading of subjective parameters was improvised for appropriate assessment and statistical analysis of various signs and symptoms to evaluate the efficacy of the test drugs. Before starting treatment, each sign and symptom was recorded according to their grades at the maiden visit and any worsening or improvement in any of the parameters was noted down at every visit of follow up till the end of the treatment. After 45 days of the treatment, the pre and post treatment values of different parameters were subjected to comparison and statistical analysis to evaluate the efficacy of the treatment.

The assessment of the safety of the treatment was done on the following parameters:

(A) Clinical assessment at every visit of follow up
(B) Hematological assessment (before and after the treatment): Hb%, TLC, DLC, ESR
(C) Biochemical assessment (before and after the treatment) – LFT (SGOT, SGPT, Total bilirubin), RFT (Blood urea, Serum creatinine), Blood sugar fasting and P P.

Results

The maximum numbers of patients were observed in age group of 30-39 yrs. The highest incidence of 28 (70%) was observed in male patients while 12 (30%) in female patients in both test and control groups. (52.5%) patients were observed as smokers while 19 (47.5%) as non-smokers. The highest incidence of 16 (40%) was observed as having environmental exposure to cigarette smoke followed by 7 (17.5%) to dust, 6 (15%) to both cigarette smoke and dust; and 11 (27.5%) were not exposed to any noxious environmental exposure. The highest incidence of 24 (60%) was observed in lower class (IV). A maximum of 25 (62.5%) patients were observed having Balghami mizaj.

Cough, sputum production, breathlessness, wheezes, chest X-Ray findings were assessed and graded as severe, moderate, mild and absent and were coded as 3, 2, I and 0, respectively. The median scores of parameters were assessed on baseline and on 45th day of the treatment. The median scores of cough, sputum production, breathlessness and wheezes in both Groups, A and B, were compared statistically using Mann-Whitney test ‘U’ for intergroup comparison, the median scores at 45 day in test and control were significantly reduced (p<0.001). Results are summarized in Table 1.

The severity of FEV1 % predicted, FEV1/FVC % and PEF was assessed and graded as per “GOLD scale”. The Mean ± SEM score for FEV1 % predicted in control group was 54.434 ± 6.115 on baseline and 62.018 ± 6.588 on 45th day, whereas in group test group) the Mean ± SEM score of FEV1 % predicted was 49.434 ± 3.644 on 0 day and 70.248 ± 3.619 on 45th day. When Mean ± SEM scores of predicted % of FEV1 in both Groups, were compared statistically using student’s ‘t’ test, it was found that the difference between the Mean ± SEM score of test group at 45th day compared with baseline was very

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Test 0 day</th>
<th>Test 45th day</th>
<th>Control 0 day</th>
<th>Control 45th day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cough</td>
<td>2.5(3, 2)</td>
<td>0(1, 0)***</td>
<td>2(3, 2)</td>
<td>1(2, 0)***</td>
</tr>
<tr>
<td>Sputum production</td>
<td>2(3, 2)</td>
<td>0(1, 0)***</td>
<td>2(3, 2)</td>
<td>1(2, 0)***</td>
</tr>
<tr>
<td>Breathlessness</td>
<td>2(3, 2)</td>
<td>0(1, 0)***</td>
<td>2(3, 1)</td>
<td>1(2, 0)***</td>
</tr>
<tr>
<td>Wheezing</td>
<td>1(3, 0)</td>
<td>0(1, 0)***</td>
<td>1(1, 0)</td>
<td>1(1, 0)</td>
</tr>
<tr>
<td>Crepitations</td>
<td>0(1, 0)</td>
<td>0(0, 0)</td>
<td>0(1, 0)</td>
<td>0(1, 0)</td>
</tr>
</tbody>
</table>

n=20 in each group, test used: Mann-Whitney test for intergroup comparison and Wilcoxon matched pairs, signed rank test for intra group comparison; * means compared with respect to Control Group, ** compared with respect to Test Group. *** p<0.001, ** p<0.01
significant (P<0.01). The Mean ± SEM score of FEV1/FVC % in control group was 75.895 ± 3.219 on baseline and 77.704 ± 3.257 on 45th day; whereas in Test group the Mean ± SEM score of FEV1/FVC % was 70.212 ± 4.248 on 0 day and 79.704 ± 2.173 on 45th day. When Mean ± SEM score for FEV1/FVC % in both Groups, were compared statistically using student’s ‘t’ test, it was found that the difference between the Mean ± SEM score of Test group at 45th day compared with baseline was very significant (p<0.019). The Mean ± SEM score of PEF was 70.212 ± 4.248 on 0 day and 79.704 ± 2.173 on 45th day. When Mean ± SEM score of PEF in both Groups were compared statistically using student’s ‘t’ test, it was found that the difference between the Mean ± SEM score of Test group at 45th day compared with baseline was significant (P<0.05). While no significant difference was found in intergroup comparison (p>0.05). Results are summarized in Table 2.

**Discussion**

**Sual** (cough) is the quintessential feature of **Warme Shoab Muzmin**. It is produced due to irritation of **madda raddiya** which is **lazae** (irritant) in nature and provokes inflammation in the respiratory tract. There is hyperplasia of goblet cells which produce excessive amount of mucus causing cough. Persistent exposure to noxious stimuli (smoke and gases) leads to classical pathological changes in respiratory tract which include inflammation in mucus membrane and over activity of mucous producing goblet cells. These features constitute the specific characteristic of **Warme Shoab Muzmin**. Breathlessness is a consistent but late feature of Warme Shoab Muzmin. Due to **Asbabe badiayah** (smoke, dust, fumes, cold air, etc.), inflammation creeps into respiratory tract, followed by hypersecretion of **ratoobate balghami**, pooling and clogging of **urooge khashna** (bronchioles) and development of **zeequnnafas** (breathlessness)\(^{11,12}\). Wheezes are the manifestation of narrowing and obstruction in airways due to inflammation and reduce with the reduction in this active pathological process. Prominent bronco-vascular markings are considered a reliable characteristic feature of **Warme Shoab Muzmin** developed due to bronchial inflammatory pathology and incipient pulmonary artery hypertension.

The ingredients used in the test formulation possess **Muhallil** (anti-inflammatory), **Munaffis** (expectorant), **Mulatiff** (demulcent) and **mukhrije balgham** (expectorant) properties\(^{13-19}\). Due to these properties, the inflammation in the respiratory tract is controlled and the consistency of mucus is modified to enable it to expectorate easily. The pooled up mucus secretions in the form of **ratoobate radidiyah** are expectorated after optimising their consistency, by the action of **mukhrije balgham**. **Muhallil** drugs decrease the inflammation and thus stop further production of sputum leaving the respiratory pathways clear and patent. With the reversal of pathology, the airways become clear and patent, thus reducing the breathlessness and wheezing as soon as the inflammation and obstruction are controlled. The beneficial effect of test formulation is corroborated by the use of these drugs in a variety of respiratory diseases like **sual** (cough), **zatuljanab** (pleurisy), **zeequnnafas** (bronchial asthma), etc. by eminent Unani scholars\(^{11,13,16}\).

The spirometric measures of FEV\(_1\) predicted %, FEV\(_1\)/FVC % and PEF assess the extent of bronchial obstruction and conversely, available space for air transaction in the lungs. **Warme Shoab Muzmin** affects bronchial space for air due to inflammation,

<table>
<thead>
<tr>
<th>Table 2 – Effect of Unani formulation on PFT (Mean ± SEM)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PFT</td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>FEV(_1), Pred. %</td>
</tr>
<tr>
<td>FEV(_1)/FVC %</td>
</tr>
<tr>
<td>PEF</td>
</tr>
</tbody>
</table>

\(n=20\) in each group, statistical test used: Student’s ‘t’ test; *compared with respect to Test Group C vs. T; (p>0.05), considered not significant. T\(_{45}\) vs. C\(_{45}\) (p>0.05), considered not significant.

*p < 0.05 compared with respect to T\(_0\) day, Considered significant.
narrowing, air trapping during expiration and excessive sputum. Present study evaluates the efficacy of test formulation for the enhancement of available free space for air transaction in Warme Shoab Muzmin patients. The same was compared with standard drug Ambroxol. But test formulation brings the available space to near normal as FEV\textsubscript{1} predicted % was ≥ 75 in most of the patients of test group after treatment. Moreover, there was significant increase in FEV\textsubscript{1}/FVC % and PEF. Thus, this study proves test formulation as better deobstruent (mufatteh urooq khashna) in comparison to Ambroxol. The efficacy progresses from 0 day to 45th day in graded manner, which suggests the consistency and presence of this effect. However, further studies are needed to evaluate this drug in specific groups like children, co-morbid conditions and pregnant women and also for longer durations so as to establish this drug with stronger evidence for its global clinical use.

Conclusion

The overall effect of the test drug was found encouraging in the treatment of Warme Shoab Muzmin. Significant improvement was observed in cough, sputum production, breathlessness, wheezes, X-Ray chest findings and values of predicted FEV\textsubscript{1} %, FEV\textsubscript{1}/FVC and PEF in test group in comparison to standard control group.

No clinically significant side effects were observed in test group and overall compliance to the treatment was found excellent. These results conclude that the test drug is safe, effective and wholesome than the Ambroxol in the treatment of Warme Shoab Muzmin.

References