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Evaluation of the clinical efficacy of a poly herbal Unani formulation in Warm-e-shoab muzmin (chronic bronchitis)

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CASE REPORT

ABSTRACT

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In the present study, efficacy of a Unani formulation in chronic bronchitis was reported and provided the scientific basis on clinical parameter. In this study 40 patients were randomly selected into two groups. The first group (n=20) was of test study and other group (n=20) for placebo study. Both, placebo and test groups were received 3 grams of sample in powder form twice daily for four weeks by oral route. Severity of cough, sputum, breathlessness, wheezing, peak expiratory flow rate (PEFR) and chest X-ray at the beginning and the end of treatment were assessed. The test drug showed a significant improvement as compared to placebo.

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INTRODUCTION

The warm-e-shoab muzmin (chronic bronchitis) is an important public health problem worldwide (Ball and Make, 1998). It is one part of chronic obstructive pulmonary disease (COPD) and proceeds to form emphysema. Chronic bronchitis and emphysema both commonly called COPD which is fourth leading cause of death in United State of America. In developed countries, the prevalence of chronic bronchitis ranges from 13-17 % of chronic inflammation in the bronchi (medium-size airways) of lungs (Ball and Make, 1998). It is generally considered one of the two forms of chronic obstructive pulmonary disease (COPD). It is defined clinically as a persistent sual (cough) that produces sputum (phlegm) and mucus, for at least three months in two consecutive years. Sual is described as a disease in Unani literature. But in modern medicine it is described as a symptom of respiratory disease. American thoracic society defined chronic bronchitis in clinical terms as chronic productive cough for three months in each of two successive years in a patient in whom other causes of chronic productive cough have been excluded (American Thoracic Society, 2005). Medical research council defined chronic

bronchitis in epidemiological studies as the presence of chronic productive cough on most days for three months, in each of two successive years, in patient whom other causes of chronic cough have been excluded. There are four types of chronic bronchitis such as simple chronic bronchitis, mucopurulent chronic bronchitis, asthmatic chronic bronchitis, and chronic obstructive bronchitis. World health organization divided the severity of chronic bronchitis on the following stages. Stage 0-at risk: chronic cough with sputum production, PFT normal. Stage I-mild: chronic cough with sputum production but mild limitation in airflow and mild changes in pulmonary function tests- PFT. Stage II-moderate: worsening of airflow that leads to shortness of breath with excretion, PFT shows marked limitation. Stage III-severe: severe air flow limitation, PFT get markedly abnormal. Bronchitis the median prevalence of chronic bronchitis was 2.6% across countries (Cerveri, et al., 2001). It is a common disease that affects from 10-25 % of adult population (Reynolds, 2000). In India 5 % males and 2.7% females are affected. Over all male: female ratio is 1.6: 1 (61.6%). The higher prevalence in male is due to habit of tobacco smoking (Jindal et al., 2001). The management of chronic bronchitis is one of the most difficult problems

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encountered in daily practice. In view of increasing side effect and limited scope of allopathic drugs, the need is to evaluate the efficacy medicine of Unani system on modern scientific parameters through clinical studies. The role of Unani herbal drugs in treating such disorder is well recognized in Unani literature.

The poly herbal Unani formulation contains the ingredients i.e. Kakra singhi (*Pistacia integerrima*), Asl-us-Soos (*Glycyrrhiza glabra*) (Agarwal, 1990), Filfil siyah (*Piper nigrum*) (Dymock et al., 1976) Jawakhar (Salt of Barley) in 4:2:2:1 ratio respectively have very effective role in the treatment of *warm-e-shoab muzmin*. All the drugs are use full in sual (cough). The objective of these studies was to evaluate the safety and efficacy of Unani formulation in the treatment of chronic bronchitis. The pharmacological activities of these drugs are given in table 1.

Table 1. Pharmacological activity of selected Unani drugs for clinical tria.

Name of the plant	Reported pharmacological activity & therapeutic use
Kakra singhi (<i>Pistacia integerrima</i>)	Anti-inflammatory, expectorant, stimulant, chronic bronchitis, Asthama (Anonymous, 1995; Rafeeque, 1985; Nadkarni, 1989; Kirtikar and Basu, 1987; Ghani, 1917)
Asl-us-Soos (<i>Glycyrrhiza glabra</i>)	Expectorant, Anti-inflammatory, cough, Asthama, Hoarsenss of voice, Bronchitis (Kabiruddin, 1916; Ibn Baitar, 1999; Agarwal, 1990; Dymock et al., 1976; Anonymous, 2000)
Filfil siyah (<i>Piper nigrum</i>)	Cough, asthma, Bronchitis (Kirtikar and Basu, 1987; Anonymous, 2000; Ghani, 1917)
Jawakhar (Salt of barley)	Expectorant, asthma, cough (Rafeeque, 1985; Ghani, 1917; Kabiruddin, 1916)

DISCUSSION

The percentage change in cough was found to be 58.33% and 15.83% in the test group and control group respectively at the end of 4 weeks treatment (Fig.1). The improvement in cough with test was extremely statistically significant at the end of treatment as compared to placebo ($P \leq 0.001$). The percentage change was found to be 49.58% and 3.75% in sputum in the test group and control group respectively at the end of 4 weeks treatment (Fig. 2). There was no statistical significant reduction in severity of sputum in control group after 4 weeks treatment ($P \geq 0.005$), where as it was found to be statistically significant in the test group ($P \leq 0.001$). Breathlessness was changed by 36.25% and 1.25% in the test group and control group respectively at the end of 4 weeks treatment (Fig. 3). There was no statistical significant reduction in breathlessness in control group ($P \geq 0.005$), where as it was found to be statistically extremely significant after 4 weeks in the

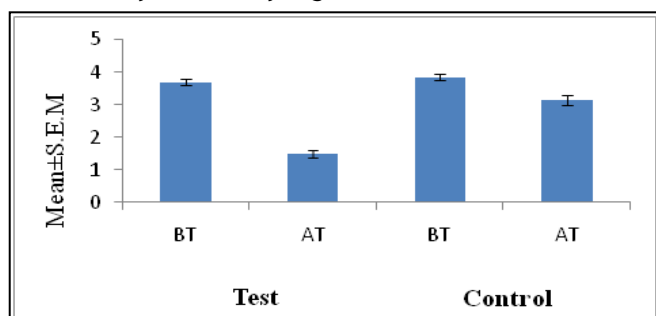


Figure 1. Effect on cough in both groups.

CASE REPORT

Forty patients who attended Majeedia Hospital, Jamia Hamdard (University), New Delhi, were selected for study. They were all thoroughly examined and diagnosed of *Warm-e-shoab muzmin* and confirmed by detailed history record which included age, sex, dietary habit (especially tobacco smokers) and drug. The physical and general examination of each patient was carried out to assess of the patient. To assess the efficacy and safety of a Unani formulation the patients were divided in two groups; test groups, controlled groups, both administered 3 grams of formulation in powder form twice daily orally to patients of moderate to severe, stable chronic bronchitis.

test group ($P \leq 0.001$). After study the percentage change was found to be 40% and 7.5% in wheezing in the test group and control group respectively, at the end of 4 weeks treatment (Fig. 4). There was no statistical significant difference in wheezes in control group after 4 weeks treatment ($P \geq 0.05$), where as it was found to be statistically significant after 4 weeks in test group ($P \leq 0.01$). The percentage of change was 11.2% and 0.24% in peak expiratory flow rate (PEFR) in the test group and control group respectively, at the end of 4 weeks treatment (Fig. 5). Placebo did not produce statistical significant changes in PFER the end of 4 weeks treatment ($P > 0.05$), where as test drug produce significant increase in PFER of 11.2%. The percentage of change was 6.66% and 2.5% in Chest X-Ray in the test group and control group respectively at the end of 4 weeks treatment (Fig. 6). There was no statistically significant improvement in both groups after the treatment in chest X-Ray ($P > 0.05$).

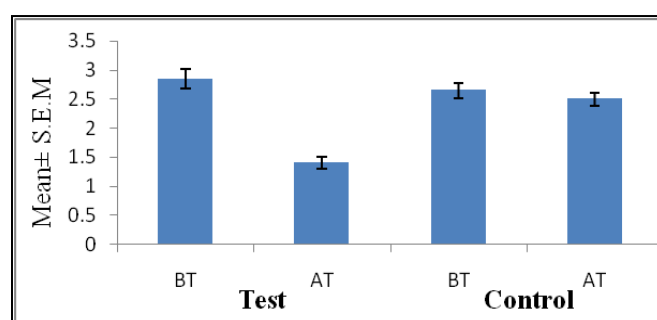


Figure 2. Effect on severity of sputum in both groups.

These changes were extremely significant ($P \leq 0.001$). The improvement in assessed parameters with test drug was considered significant against the placebo ($P \leq 0.05$). In assessment of safety, there was no statistical significant difference ($P > 0.05$) in haemoglobin (Hb), total leukocyte count (TLC), differential leukocyte count (DLC), kidney function tests (KFT) and liver function tests (LFT) in both groups. These results showed that test drug has no effect on Hb, TLC, DLC, KFT and LFT.

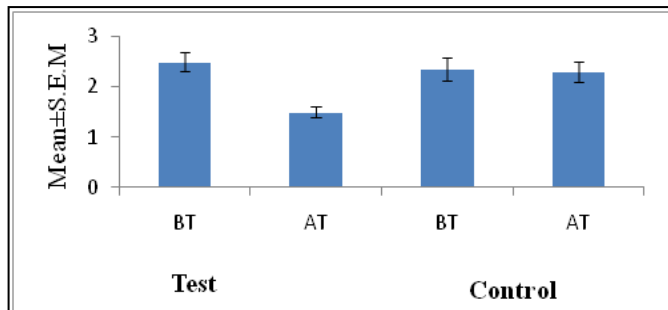


Figure 3. Effect on breathlessness in both groups.

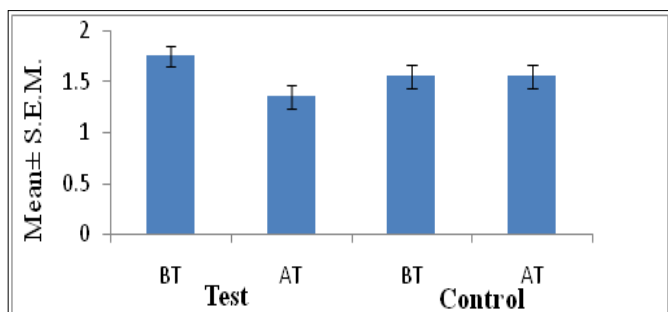


Figure 4. Effect on bronchi/wheeze in both groups.

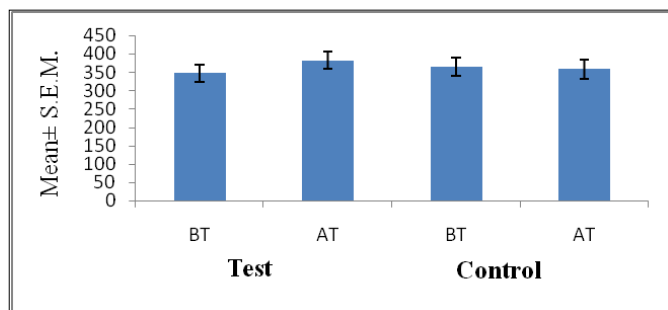


Figure 5. Effect on PFER (L/min) in both groups.

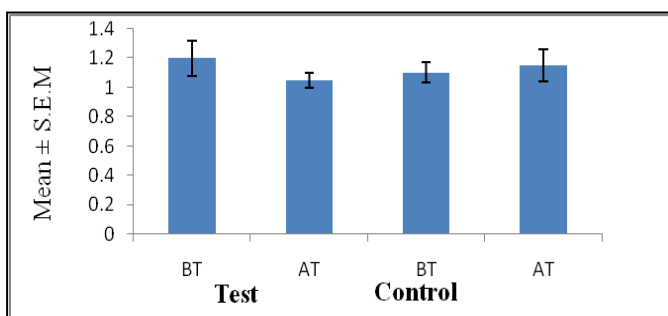


Figure 6. Effect on CXR (PA) (L/min) in both groups

CONCLUSION

There is strong evidence from this study that the test drug has the significant role in chronic bronchitis. The role of Unani herbal drugs in treating such disorder is well recognized in Unani classical literature.

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CONFLICT OF INTEREST

None declared.

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