Clinical Evaluation of Efficacy of Asal-us-Soos,Alsi,Irsa, Barg-e-Adoosa and Honey on Chronic Bronchitis: A Preliminary Study

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Abstract

In the present study, efficacy of a Unani drug preparation (Asal-us-Soos, Alsi, Irsa, Barg-e-Adoosa and Honey) has been assessed on 70 cases of chronic bronchitis. Among these 60 completed the course of study, the results were found to be highly significant. Further investigations are suggested.

Keywords: Chronic Bronchitis, Sual Muzmin, Unani Medicine.

Introduction

Chronic bronchitis is a cough phlegm syndrome. The term was introduced into the medical literature early in the 19th century and was recognized as an inflammatory disease of the airways (Sidney, 2006). The Ciba Guest Symposium published in 1959 provided definition of chronic bronchitis as "chronic or recurrent excessive mucous secretion in the bronchial tree". The definition of chronic bronchitis was quantified by epidemiologists as "the presence of chronic productive cough for at least three consecutive months in two consecutive years with other causes of chronic productive cough ruled out" such as pulmonary tuberculosis, carcinoma of the lung, bronchiectasis, cystic fibrosis and congestive heart failure (Chabra, 2009; Fauci, 2008; Fishman, 2007; Fletcher, 1984; Robert, 2005).

In developed countries, cigarette smoking is responsible for 85 to 90% cases of chronic bronchitis (Robert, 2005; Cohen, 1980; Goel, 2007; Jindal, 2006; Sharma, 2005).

Cigarette smokers have a higher prevalence of respiratory symptoms and lung function abnormalities, a greater annual rate of decline in FEV_1, and a greater COPD mortality rate than nonsmokers (Mannino, 2006; Anthoney, 2005). Ancient Unani physicians have described chronic bronchitis under the heading of *SualMuzmin* (chronic cough) (Khan, 1983; Khan, 1939; Jurjani, 1902; Arzani, 1955).

According to the report of National Heart, Lung, and Blood Institute US Department of Health and Human Service, March 2003, 9.2 million adults aged 25 and older reported being diagnosed with chronic bronchitis and about 24 million adults have impaired lung function. About 119, 054 adults ages 25 and older died from COPD in 2000 (Anonymous 2003).The total estimated cost of COPD treatment in 2002 was $ 32.1 billion. A survey conducted by the

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Copenhagen City heart study showed the prevalence of chronic bronchitis at around 10 percent in Copenhagen (Peter, 2003).

The most consistent pathologic correlate is the hypertrophy of the bronchial mucosa. Chronic cough, expectoration and breathlessness are the cardinal symptoms of the disease (Anthony and Douglas, 2005).

In Unani medicine, *Muhallil Auram* (anti-inflammatory), *Munaffis Balgham* (expectorants) and *Mulattif* (mucolytics) are given in the treatment of chronic bronchitis (Khan, 1983; Khan, 1939; Jurjani, 1902; Arzani, 1955).

In allopathic system of medicine, corticosteroids & bronchodilators are used in the treatment of chronic bronchitis (Mannino, 2006). Corticosteroids have serious side effects when used for a long period and bronchodilators are not the permanent solution. So there is a need for a permanent remedy which the patients can take for a long period safely.

Unani system of medicine, a traditional system, has a successful treatment of chronic bronchitis. Unani literatures show that *Asal-us-Soos, Alsi, Irsa, Barg-e-Adoosa*and Honey are effective in chronic bronchitis (Alam, 2011; Khan, 1933; Baitar, 1999). Holy Quran described the honey as, a drink of varying colors, wherein is healing for mankind. Verily, in this is indeed a Sign for people who think (Qur'ân 16:68-69). In addition, the Prophet Mohammad said: "Honey is a remedy for every illness and the Qur'ân is a remedy for all illness of the mind, therefore I recommend to your remedies, the Qur'an and honey" (Qur'ân 16:68-69, Bukhari, 2000; Ilahi, 2010). Hence an attempt was made to test their efficacy clinically.

Material and Method

The present study was a simple observational study conducted in OPD/IPD of Ajmal Khan Tibbiya College Hospital, under the Department of Moalajat, Aligarh Muslim University, Aligarh. Acomprehensive protocol was chalked out and was put forth for ethical clearance from the ethical committee of the Department. 70 subjects were randomly selected amongst the patients provisionally diagnosed to be suffering from chronic bronchitis and after fulfilling all the inclusive and exclusive criteria as mentioned below, among them 60 cases completed the course of study. 10 (14.2%) cases were dropped from the study as theycannotfollow the protocol.

Inclusion Criteria

1. Patients in the age group of 30 to 65 years.

2. Patients presenting cough with expectoration, on most days of at least three months of two consecutive years.
3. Patients with the history of smoking.
4. Patients with the history of smoke exposure.
5. Patients with harsh vesicular breathing with prolong expiration and/or bilateral rhonchi on clinical examination.
6. Patients with positive radiological diagnosis of chronic bronchitis.
7. Patients with FEV_1 < 80% of predicted value.
8. Patients with FEV_1/FVC ratio < 70%
9. Patients who were clinically stable.

Exclusion Criteria

1. Patients below 30 years and over 65 years.
2. Patients having evidence of cor-pulmonale.
3. Patients in acute exacerbation of COPD.
4. Patients with other associated diseases like left ventricular failure, mitral stenosis, other cardiac diseases and peptic ulceration etc.
5. Patients with previous documented response to oral steroids or who had been on oral and or inhaled steroids in the past 3 months.
6. Patients with personal or family history of allergy.
7. Patient having Hb% less than 10.
8. Patients having AFB positive.
9. Patients having wastage of muscles.
10. Patients having compromised immunity.

Selection of Drugs

All the ingredients of the test combination singly or, as a constituent of many pharmacopeal compound drugs, are in use in bronchitis and other diseases of chest and respiratory system since long past in Unani system of medicine. Physicians at Ajmal Khan Tibbiya College (AKTC) Hospital are frequently prescribing this combination in chronic bronchitis. Further, a combination containing all the ingredients except Berg-e-Adoosa is prepared by the hospital pharmacy for distribution of the OPD/IPD patients. The hospital data suggest

that the drug is effective in cases of chronic bronchitis. In view of its successful practice by the physicians at AKTC hospital who have described its promising effects in bronchitis and other respiratory diseases are 'age old' practice of the ingredients of the combination of Unani medicine (Mannan, 1999). This combination was selected to study its efficacy and safety in cases of chronic bronchitis.

Identification of Drugs

Identification of test drugs i.e. *Asal-us-Soos, Alsi, Irsa, Barg-e-Adoosa* was done by Professor S. H. Afaq, eminent pharma-cogonist, Department of Ilmul Advia, Ajmal Khan Tibbiya College, Aligarh Muslim University, Aligarh, while pure honey was purchased from Agro Honey, Gramudhyog Seva Samity, Malic Enclave, Nakasia, Bareilly, U.P. *Asal-us-Soos, Alsi, Irsa* and *Barg-e-Adoosa* were purchased from Dawakhana Tibbiya College, AMU, Aligarh.

The drugs also processedin pharmacy section of the Ajmal Khan Tibbiya College Hospital forthe removal of impurities and made them *Neemkoob Shuda* (semi grinded form) for joshanda preparation. The Joshanda was prepared by drugs in equal quantity of 4 grams each in 100 ml of water. The joshanda was boiled till the water remained half in quantity. The filtrate was superadded with 20 ml of honey. Patients were given the prepared joshanda twice a day on an empty stomach. No concomitant treatment was allowed during the study.

The duration of the study was 42 days. The weekly follow up of the cases was scheduled for the assessment of efficacy of the drugs.

Safety assessment: The safety of the drugs treatment was assessed through non-occurrence of any toxic or adverse effect during the treatment period on the following parameters:

Complete Haemogram, RFT, LFT, Blood Sugar.

Efficacy assessment: The assessment of the efficacy was determined on the subjective and objective parameters as follows:

Subjective Parameters:

Decrease in the cough	Decrease in sputum expectoration
Improvement in breathlessness	Disappearance of rhonchi
Improvement in general condition	

Objective parameters:

Increase in FEV_1 of predicted value	Enhancement of the FEV_1/FVC ratio

Statistical analysis: The observations and data collected were tabulated and statistically analyzed by applying paired t test for objective parameter and non-parametric values were calculated with applying Kruskal Wallis test.

Table 1: Effects of test drugs on the cough during follow up. n = 60

Follow up (in days)															
Group	Severity	Before treatment	After treatment												
		0 Day	7th		14th		21st		28th		35th		42nd		Net Improvement %
		No. of Patients	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	
Test Drug	Mild	15	15	0	12	20	9	40	6	60	0	100	0	100	66%
	Moderate	33	33	0	30	9.1	24	27.3	15	54.4	12	63.4	9	73	
	Severe	12	12	0	12	0	12	0	9	25	9	25	9	25	
Kruskal Wallis Value (KW)		8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	

Table 2 : Effects of test drugs on Sputum during follow up. n = 60

Follow up (in days)															
Group	Severity	Before treatment	After treatment												
		0 Day	7th		14th		21st		28th		35th		42nd		Net Improvement %
		No. of Patients	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	
Test Drug	Mild	15	15	0	12	20	9	40	6	60	0	100	0	100	59.8%
	Moderate	33	33	0	33	0	27	18.2	24	27.3	18	45.5	15	54.4	
	Severe	12	12	0	12	0	1	0	9	25	9	25	9	25	
Kruskal Wallis Value (KW)		8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	

Table 3 : Effects of test drugs on breathlessness during follow. n = 45

Follow up (in days)															
Group	Severity	Before treatment	After treatment												
		0 Day	7th		14th		21st		28th		35th		42nd		Net Improvement %
		No. of Patients	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	
Test Drug	Mild	12	12	0	12	0	9	25	6	50	3	75	0	100	61.1%
	Moderate	24	24	0	24	0	24	0	18	25	12	50	12	50	
	Severe	9	9	0	9	0	9	0	9	0	6	33.3	6	33.3	
Kruskal Wallis Value (KW)		8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	8.0	

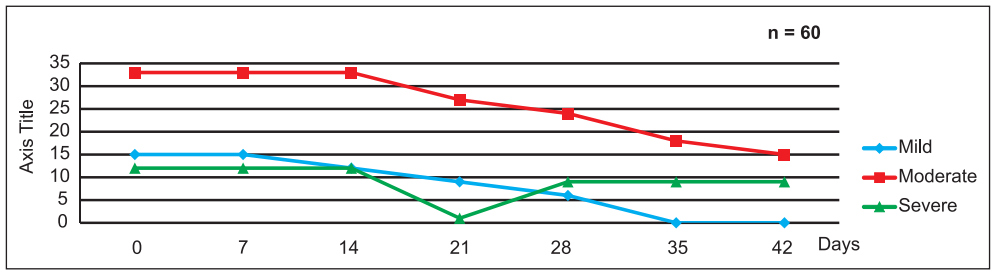
Table 4 : Effects of test drugs on Wheezes during follow up. n = 45

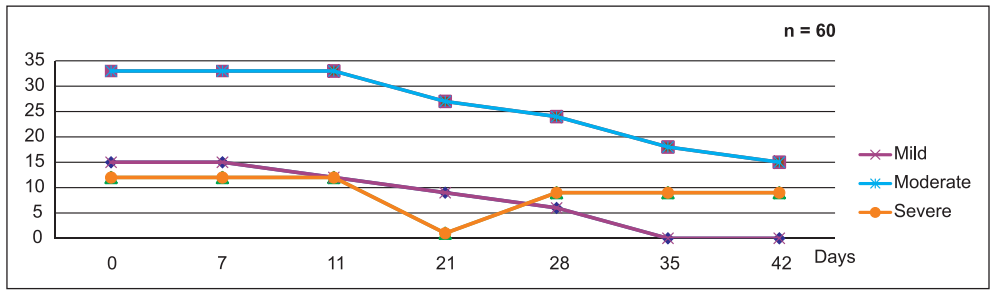
Follow up (in days)													
Group	Before treatment	After treatment											
	0 Day	7th		14th		21st		28th		35th		42nd	
	No. of Patients	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %	No. of Patients	Improvement %
Test Drug	45	45	0	45	0	39	13.3	30	33.3	24	46.7	18	60

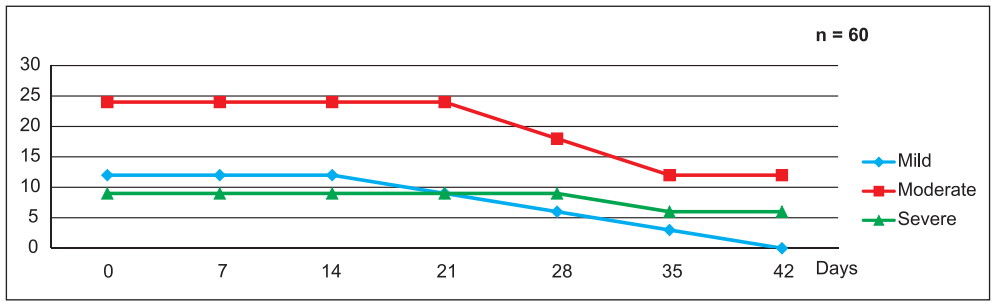
Table 5 : Effect of Drugs on FEV1 Predicted value n = 60

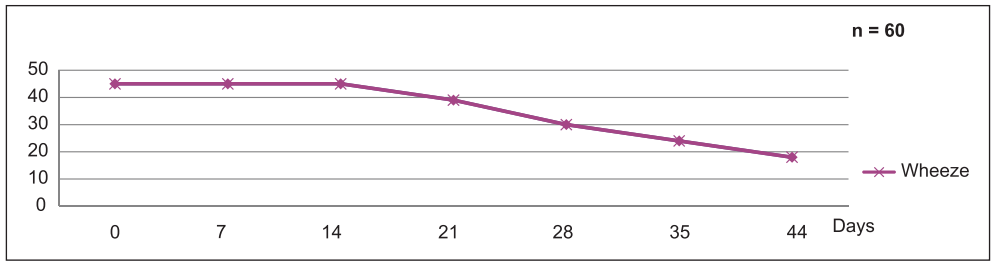
FEV1	No. of Patients	Mean FEV1 Predicted value		t value p value	Overall Mean Predicted value n = 20		t – value p – value
		Before Treatment	After Treatment		B.T	A.T	
70-79 (Mild)	15	75.0 + 3.4	86.4 + 5.7	t = 5.60 p < 0.001	62.1 + 6.9	80.6 + 5.1	t = 9.5 p< 0.001
60-69 (Moderate)	30	63.0 + 2.3	87 + 5.4	t = 3.25 p < 0.01			
50-59 (Moderately Severe)	15	55.0 + 3.9	75 + 3.0	t = 2.77 p < 0.05			

Applying paired t test for the observations recorded before and after the treatment.









Results and Discussion

The effect of the drugs on three sub groups of cough, i.e. mild, moderate and severe was observed as 100%, 73% and 25% improvement respectively. Average improvement was 66% of cases (Table and Graph 1). The important drugs in the formulation which directly suppress the spell of cough are Irsa*(Iris ensata)*, Asal-us-Soos*(Glycirrhiza glabra)* and Adoosa*(Adhatoda vasica).*They have a stabilized effect, but in combination, their cumulative effect is more important and potent then their individual effect. The base of the formulation is honey which has several properties including being demulcent, mucokinetic and having cough suppressant action on bronchoalveolar mucosa. Most probably the presence of essential oils, vacicinol, vacicinine and adhatine in Adoosa, glycyrrhizin, asparazines and a glycoside anthoxacin in Asl-us-sooos as well as the tonic and respiratory epithelium regenerator effect of honey are factors responsible for improving the drug efficacy (Rastogi *et al*., 1960-1969; 1980-1984; 1990-1994). The effects of the drug on three sub groups of sputum i.e. mild, moderate and severe were observed as 100%, 54.4% and 25% respectively. Overall improvement was 59.8% of cases (Table and Graph 2).

A remarkable improvement of 60% was noted in the severity of sputum expectoration in different categories at the end of the study (Table and Graph 2). The improvement may be contributed by mucolytic, mucokinetic and expectorant actions of *Asal-us-Soos, Irsa*and*Alsi,* as well as broncho-dilatory effects of *Adoosa*, *Alsi,* and *Irsa. Irsa* consists of vanalic and P- hydroxylenoic acid, which has anti-allergic and anti-histamic properties. It also suppresses the mucus to the mucus production (sputum). The Embinin present in *Irsa*acts as deobstractant effect besides having anti-dotal properties at various toxins and allergens (Rastogi *et al*.,1960-1969; 1980-1984; 1990-1994).

There was 100% aptness in mild cases, 50% correctness in moderate cases and 33.3% recovery in severe cases of breathlessness. Total improvement was 61.1% of cases (Table and Graph 3).

Breathlessness is due to impaired airflow in bronchial passage which is in the lumen of bronchioles due to hypertrophy of bronchial mucosa in chronic bronchitis. Also there is defective mucociliary clearance due to inactivation of cilia. The accumulation of mucous takes place and ultimately there are breathing difficulties i.e. breathlessness, hypoxemia etc. In our formulation, *Adoosa*is a known bronchodialator having bromhexin as alkaloid which is a potent mucolytic agent (Rastogi *et al*., 1960-1969; 1980-1984; 1990-1994). The mucolytic as well as bronchodilatory effect improves mucociliary clearance action and facilitates the air conductance. The *Irsa*, due to its membrane stabilizing action, along with honey, makes the lumen healthier and helps in rejuvenation process of bronchoalveolar epithelium. Breathlessness was categorized as mild, moderate and severe according to the Modified Medical Research Council questionnaire(Bestall,1999). The average improvement in breathlessness was 61% of cases(Table and Graph 3).

Wheeze or rhonchi were present in all the 45 cases and there was 60% improvement in them at the end of the study (Table and Graph 4).

The concept of Munzij is very vital in the expulsion of all viscid humours. The test drugs bear Munzij properties for khiltebalgham (phlegmatic humour) and KhilteSawdawi (melancholic humour) which spawn noxious pathological changes leading to chronic bronchitis. The expelling effect on abnormal MawadwaAkhlat is the significant action in relieving the pathology of bronchial mucosa and bronchus contents.

The mean FEV_1 percentage predicted values recorded prior to the study were 75.0 $\pm$ 3.4, 63.0 $\pm$ 2.3, 55.0 $\pm$ 3.9 and 62.1 $\pm$ 6.9 in mild, moderate, moderatelysevere respectively. Remarkable increments of 86.4 $\pm$ 5.7, 87.0 $\pm$ 5.4, 75.0 $\pm$ 3.0 and 80.6 $\pm$ 5.1 were achieved in mild, moderate and moderately severe respectively. The difference is significant statistically ($t = 5.60$ and $p < 0.005$, $t = 3.25$, and $p < 0.01$ and $t = 2.77$ and $p < 0.05$ and $t = 9.5$ and $p < 0.001$ (Table 5). Due to the aforementioned effect of the formulation the improvement in the objective parameter was significant statistically. $t = 9.5$, $p < 0.001$) (Table 5)

Conclusion

The subjected drugs formulation showed significant preiminary results in alleviating the symptoms, signs and physical findings along with improvement in FEV_1 and FEV_1/FVC ratio without any observable side effects.

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