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Clinical study of Usr-e-Tanafus (Bronchoconstriction in COPD) & evaluation of efficacy of a Unani formulation in its management

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Abstract
Muzmin Tasuddudi Amraze Riya or Chronic obstructive pulmonary disease (COPD) is defined as a disease state characterized by air flow limitation that is not fully reversible. COPD is the third leading cause of death and affect > 10 million persons in United State. COPD is also increasing public heath importance around world. Estimate suggest that COPD will rise from sixth to the third most common cause of death worlds wide. The prevalence of COPD is higher in countries where smoking is highly prevalent. The prevalence range between 2 to 22 percent among the men and 1.2 to 19 percent women in different population based studies across India. The aim of present study is to evaluate the safety and efficacy of a Unani formulation in the treatment of COPD.

Keywords: COPD, Unani formulation, CAT score, spirometry

1. Introduction
Chronic obstructive pulmonary disease (COPD) is defined as a disease state characterized by air flow limitation that is not fully reversible and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. COPD include chronic bronchitis and emphysema. Chronic bronchitis is defined clinically as productive cough on most days for at least 3 consecutive months per year for at least 2 consecutive years. Emphysema is defined pathologically as permanent enlargement of air spaces distal to the terminal bronchioles accompanied by destruction of the alveolar walls and absence of associated fibrosis 2. COPD is the third leading cause of death and affect > 10 million person in United states. COPD is also increasing public heath importance around world3. Estimate suggest that COPD will rise from sixth to the third most common cause of death world wide by 2020. The prevalence of COPD is higher in countries where smoking is highly prevalent. The prevalence range between 2 to 22 percent among the men and 1.2 to 19 percent women in different population based studies across India.4 As on 2016, three out of five leading causes of mortalities constitute non–communicable disease where as COPD is the second biggest cause of death in India.
Muzmin Tasuddudi Amraze Riya is a term which has been literally translated by the contemporary unani physicians in an attempt to explain the COPD entity applicable to present day etymology while going through unani literature, the term *Muzmin Tasuddudi Amraze Riya* has not been mentioned as such but it can be related to clinical features of *Su'aal barid maddi, Su'aal ratab and Rabu martoob* as described by Ibne sina, Azam khan, Ajmal khan [5-8].
There are several single as well as compound unani drugs which are in use for centuries for effectively treating the disease but many of them have not been evaluated clinically on scientific parameters further the limitation of management of COPD available in modern medicine necessitate a scientific search for safe, effective and convenient medication for the disease.
Keeping this in view, the present study was designed to evaluate the efficacy of a compound Unani formulation in *Usr-e-tanafus* (bronchoconstriction) in COPD.

2. Materials and Methodology
The study titled 'Clinical Study on Usr-e-Tanafus (Bronchoconstriction in COPD) & Evaluation of Efficacy of a Unani formulation in its treatment' was carried out at

Deptt. of Moal'ajat, Majeedia Hospital, Faculty of Medicine, Hamdard University, New Delhi. Patients were enrolled from the out-patient & in-patient department of Majeedia Hospital on the basis of history, physical examination and investigations. Before starting the study, the research protocol was duly approved by Institutional Ethical Committee (IEC) as per the norms. Patients were randomized into Test and control groups by Lottery method of randomization. Patients who were on any other drug (Allopathic, Ayurvedic, *Unani* etc) for this disease were stopped 15 days before enrolling into the study and were not allowed to take any other drug for COPD during the study period.

3. Criteria for selection of patients

3.1 Inclusion criteria

1. Patients with history of

a) Cough for more than 3 months for two conseqative years
b) Expectoration
c) Exertional Dyspnoea
d) wheezing

Patient in age group 12-60 years
Patients with PEFR (40%-70%) of predicted value as per age & height.
Patients from environmentally polluted & exposed areas.
Patient of either sex
Patient who were clinically stable
Diagnosed cases of COPD

3.2 Exclusion criteria

- Patient below 12 years and over 60 years
- Patient in acute exacerbation of disease
- Patient of severe or very severe type of COPD
- Patients on steroids
- Pneumonia
- Tuberculosis
- Lung carcinoma
- Pregnant & lactating mothers

3.3 Subjective parameter

- Dyspnoea
- Cough with sputum
- Tightness in chest

3.4 Objective parameter

- Clinical examination
- Wheezing & Rhonchi
- Chest X-ray
- Pulmonary Function Tests

4. Investigations

A set of investigations were carried out in all the patients to include or exclude from the study and to assess the efficacy and effect of test and control drug on different paramaters which included:

Complete blood counts (CBC)
Erythrocyte sedimentation rate (ESR)
Fasting Blood sugar (FBS)
Lipid profile
Liver function test (LFT)
Kidney function test (KFT)
Urine examination
E.C.G.
Chest X-ray
Pulmonary Function Tests

All the above mentioned investigations were carried out in all the patients before the commencement of the study and after the completion of the study.

5. Consent of the patient

Before enrolling the patients for the study, every patient was provided a set of specially designed Information Consent Form (ICF) which included all the relavant information about the study, investigations, drug, method of treatment and follow-up plan with all the options to ask any query regarding the study. After that when the patient signed the Information Consent Form (ICF), the treatment was started.

6. Study design

A randomized, single blind, placebo controlled clinical study.

7. Sample size

A sample size of 30 patients with 15 in test and 15 in control group.

8. Allocation of group

Lottery method of randomization was used for allocation of group with Group A as Test group and Group B as control group with 15 patients in each group.

9. Assessment of Mizaj (Temperament)

Temperament of each patient was assessed as per the specially designed scale before the start of treatment.

10. Duration of study

The duration of study was 60 days in both the test and control groups.

11. Follow -up plan for patients

Follow up was done on 15^{th} day, 30^{th} day, 45^{th} day, 60^{th} day in both the groups. On every follow up, patients were assessed for improvement of their symptoms or worsening of symptoms, appearance of any new symptom, adverse drug effects if any. All the clinical parameters were checked and were recorded in Case Record Form (CRF).

12.1.1 Test drug

The test drug was a Unani formulation consisting of Rub-e-soos (Extract of *Glycyrrhiza glabra*), Barge-aroosa (*Adhatoda vesical*), Kakra Singi (*Pistacia integerrima*) in powder form.

12.2 Control drug: Placebo

12.3 Method of Preparation, Dosage and Mode of Administration of Test Drug

The test drugs were purchased from reputed herbal supplier of Delhi (Khari boali) and were properly identified by the experts in the Deptt. of Ilmul-Advia & Deptt. of Botany, Hamdard University, New Delhi. for its originality. After proper cleaning, the drugs ware grinded into a powder from the Deptt. of Pharmacy, Faculty of Medicine, Hamdard University, New Delhi. The dosage of the test drug was 6gms twice daily in the morning after breakfast and another dose in the evening to each patient with luke warm water.

12.4 Dose and Mode of Administration of Control Drug

The control drug placebo was also given powder form in the morning & evening in control group patients.

13. Safety Assessment

All the patients enrolled for the study were assesed for safety pre and post treatment protocol on following parameters:

a) Clinical check-up at every follow-up.
b) Complete Blood Picture like CBC, ESR, & Urine exam on pre (Day 0) and post treatment (Day 61) after completion of the treatment protocol.
c) Blood sugar fasting, LFT, KFT, ECG were done before (Day 0) and after treatment (Day 61).

14. Observations and Results

Table 1: Showing Age Distribution among Test group and Control group (n=30)

Age in Years	No. of cases	Percentage
15-19	2	6.66
20-24	2	6.66
25-29	3	10
30-34	5	16.66
35-39	6	20
40-44	5	16.66
45-49	3	10
50-54	2	6.66
55-60	2	6.66
Total	30	100

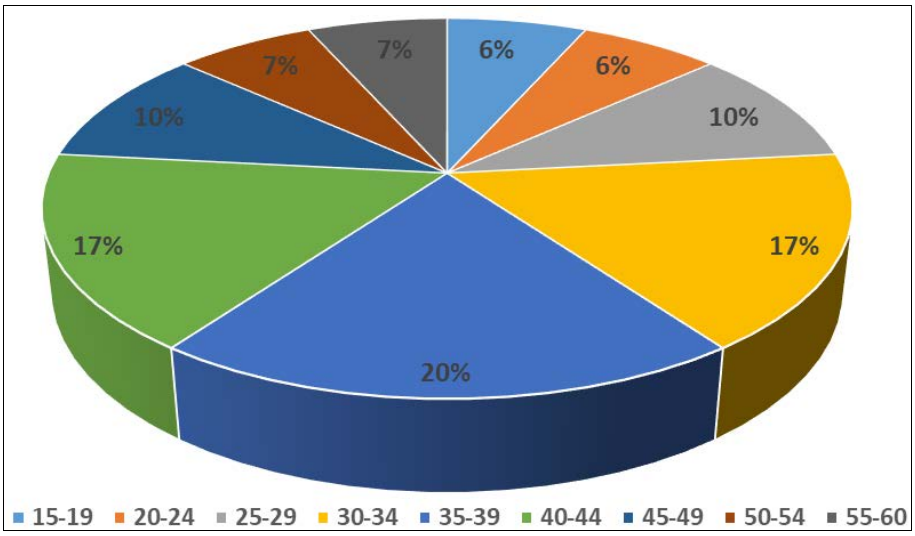

Fig 1: Age Distribution

Table 2: Showing Sex Distribution among Test group and Control group (n=30)

Sex	No. of cases	Percentage
Males	19	63.33
Females	11	36.67
Total	30	100

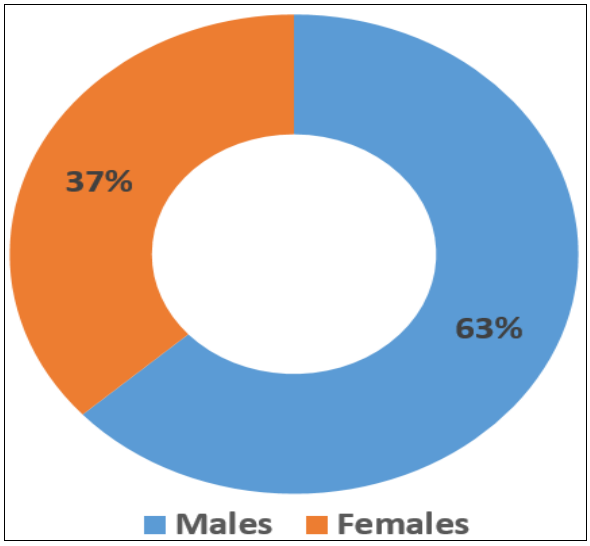

Fig 2: Sex Distribution

Table 3: Showing Mizaj of Patients (n=30)

Mizaj	No. of cases Group A	Percentage	No. of Cases Group B	Percentage
Damvi	3	20%	2	13.3%
Balghami	10	66.7%	9	60%
Safravi	2	13.3%	3	20%
Saudavi	0	0	1	6.7%
Total	15	100%		100%

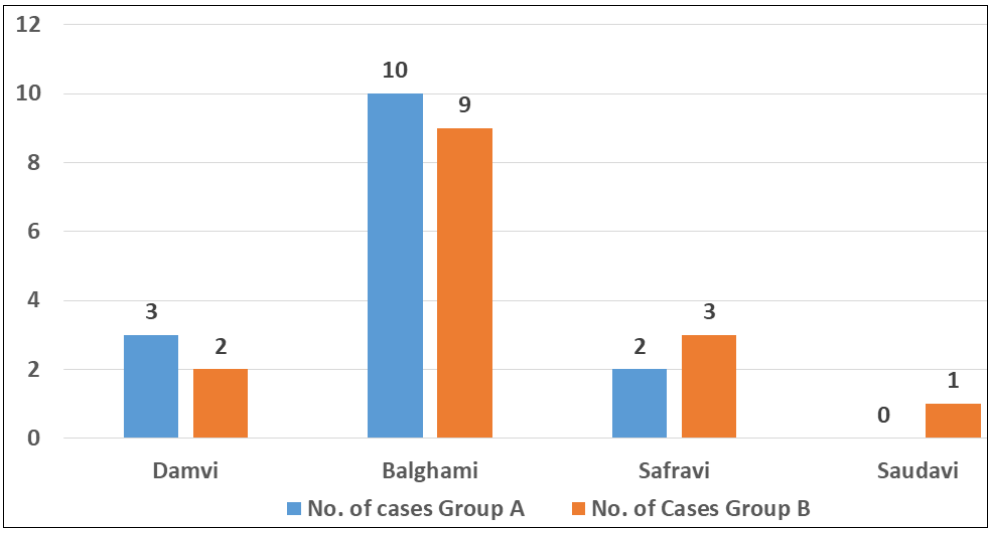

Fig 3: Mizaj of Patients

Table 4: Showing Clinical Improvement in relation to Dyspnoea in Test/control group

Symptom	No. Of Cases improved in Test Group	% age of improvement	No. of cases showed no improvement in test group	%age of cases with no improvement in test group	No. of cases improved in control group	%age of improved cases	No. of cases with no improvement in control group	%age of cases with no improvement in control group
Dyspnoea	13	86.6%	2	13.3%	2	13.3%	13	86.7%

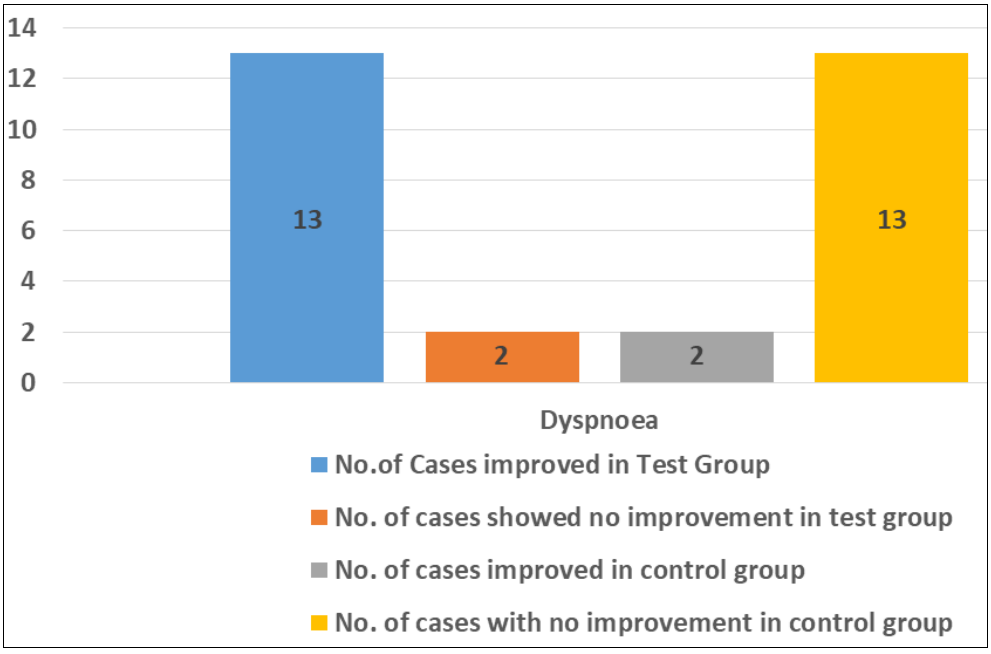

Fig 4: Clinical Improvement in relation to Dyspnoea in Test/control group

Table 5: Showing Clinical Improvement in relation to Cough in Test/control group

Symptom	No. Of Cases improved in Test Group	%age of improvement	No. of cases showed no improvement in test group	%age of cases with no improvement in test group	No. of cases improved in control group	%age of improved cases	No. of cases with no improvement in control group	%age of cases with no improvement in control group
Cough	12	80%	3	20%	4	26.7%	11	73.3%

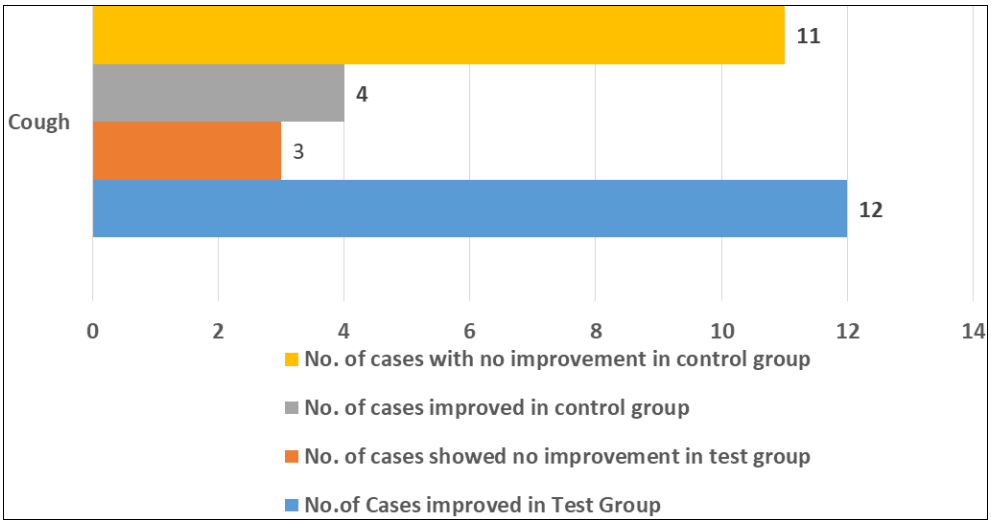

Fig 5: Clinical Improvement in relation to Cough in Test/control group

Table 6: Showing Clinical Improvement in relation to Sputum in Test/control group

Symptom	No.of Cases improved in Test Group	%age of improvement	No. of cases showed no improvement in test group	%age of cases with no improvement in test group	No. of cases improved in control group	%age of improved cases	No. of cases with no improvement in control group	%age of cases with no improvement in control group
Sputum	11	73.3%	4	26.6%	4	26.7%	11	73,7%

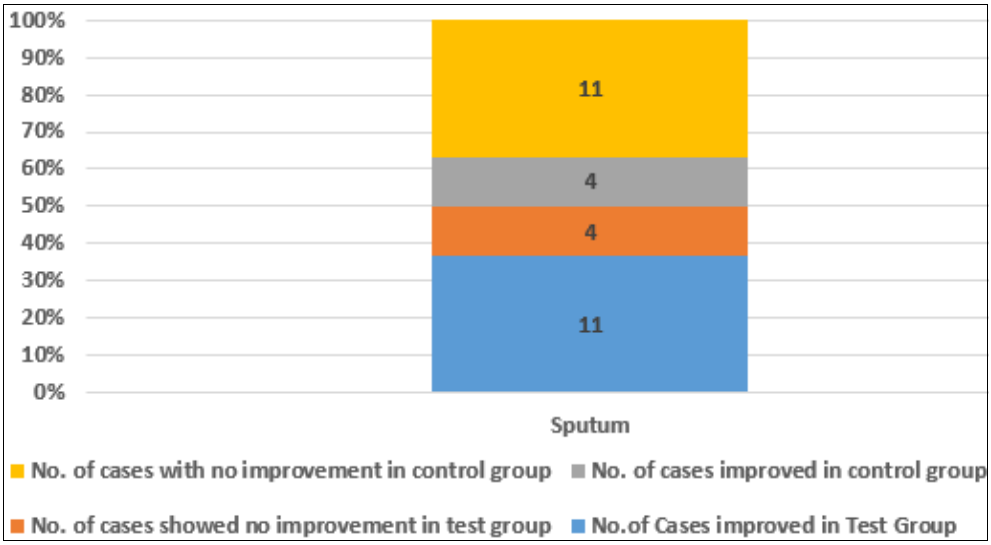

Fig 6: Clinical Improvement in relation to Sputum in Test/control group

Table 7: Showing Clinical Improvement in relation to Nocturnal Dyspnoea in Test/control group

Symptom	No. Of Cases improved in Test Group	% age of improvement	No. of cases showed no improvement in test group	%age of cases with no improvement in test group	No. of cases improved in control group	%age of improved cases	No. of cases with no improvement in control group	%age of cases with no improvement in control group
Nocturnal Dyspnoea	12	80%	3	20%	2	13.3%	13	86.7%

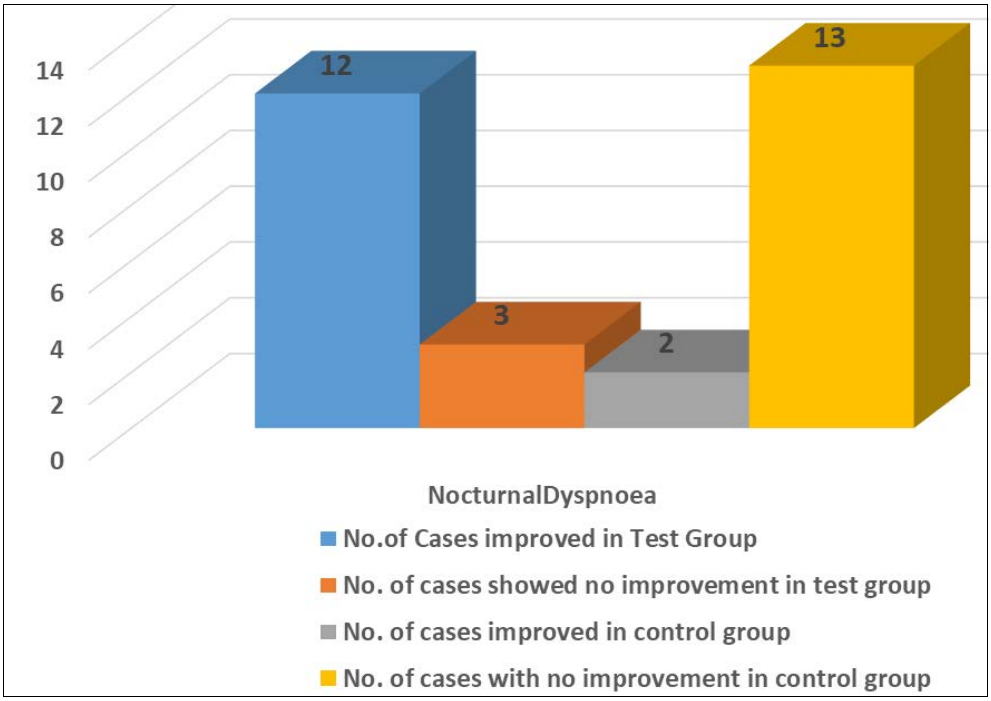

Fig 7: Clinical Improvement in relation to Nocturnal Dyspnoea in Test/control group

Table 8: Showing Clinical Improvement in relation to Tightness in chest in Test/control group

Symptom	No. Of Cases improved in Test Group	% age of improvement	No. of cases showed no improvement in test group	% age of cases with no improvement in test group	No. of cases improved in control group	% age of improved cases	No. of cases with no improvement in control group	% age of cases with no improvement in control group
Tightness in chest	12	80%	3	20%	2	13.3%	13	86.7%

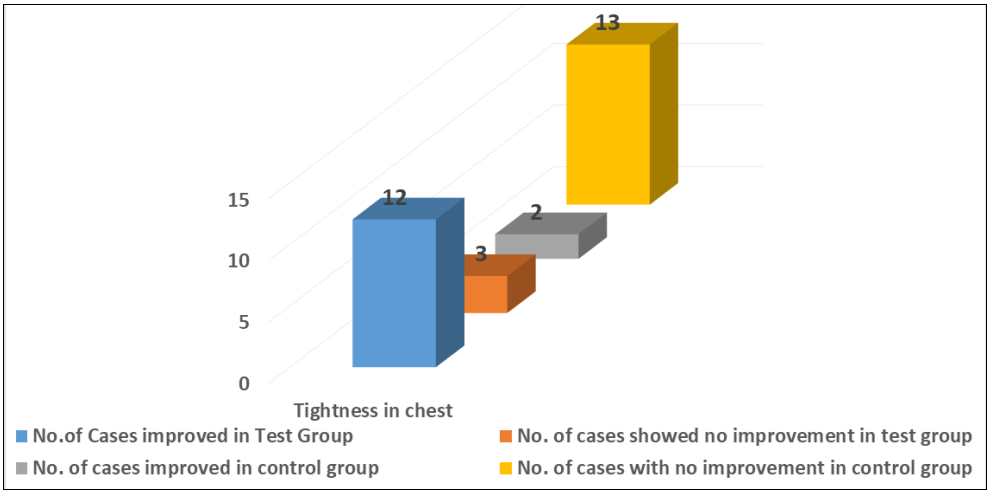

Fig 8: Clinical Improvement in relation to Tightness in chest in Test/control group

Table 9: Showing Clinical Improvement in relation to Wheezing in Test/control group

Symptom	No. Of Cases improved in Test Group	%age of improvement	No. of cases showed no improvement in test group	%age of cases with no improvement in test group	No. of cases improved in control group	%age of improved cases	No. of cases with no improvement in control group	%age of cases with no improvement in control group
Wheezing	13	86.6%	2	13.3%	2	13.3%	13	86.7%

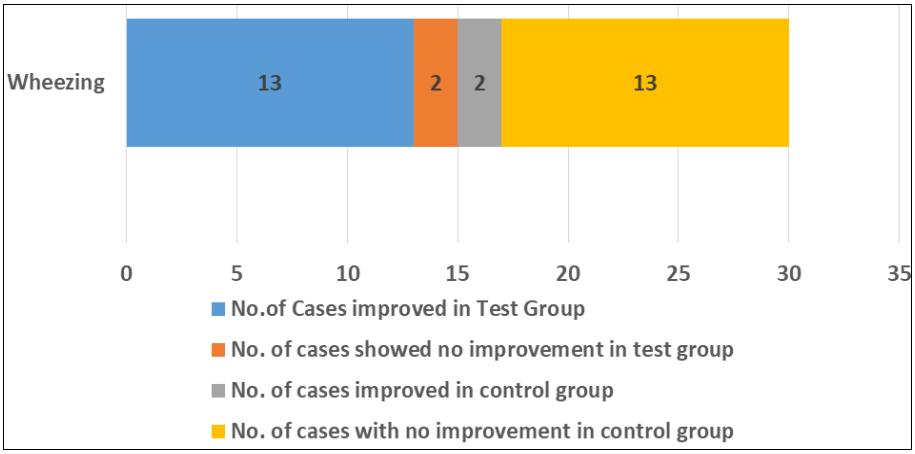

Fig 9: Clinical Improvement in relation to Wheezing in Test/control group

Table 10: Showing Lung functions (Peak Expiratory Flow Rate) before & after the treatment in Test & control groups along with significance of difference between both the groups

Function PEFR	N	Basal (x+-S.E.)	After 4 weeks x-+-S.E.
Control Group	15	284+-12.38	257+-11.8
Test Group	15	295+-17.31	342+-16.39

N=No. of cases studied (15 in each group)
X-=Mean
S.E.=Standard error of mean

15. Discussion

The present study was conducted to evaluate the therapeutic efficacy of a Unani formulation on Usr-e-Tanafus in COPD patients. A total of 30 patients were enrolled for the study and were randomly grouped and were allocated either test (Group A) or control (Group B) groups in equal distribution. After the completion of treatment protocol of 4 weeks, stastical analysis were done. Group A was given *a* Unani formulation in the form of powder in the dose of 6 gms twice daily after breakfast and after evening tea with warm water for a peroid of 4 weekdays. Group B were given placebo orally twice a day in the same form and dosage as test drug for a peroid of 60 days. The patients of both groups were followed up after every 15 days for a peroid of 60 days and recording of improvement in subjective and objective parameters were done on case record forms (CRF).

For statistical analysis, recorded data was compiled and entered in a spread sheet and then exported to data editor of SPSS version 20.0, Minitab version 14, and Graph pad prism softwares. The continuous variables like age and sex were expressed in terms of (mean ± standard deviation) and categorical variables were expressed in terms of frequency and percentage. Student's independent t-test was employed for inter-group analysis of continuous data and for intra-group analysis paired t-test was applied. Wilcoxon signed rank test was used for intra group analysis of ordinal data. Chi-square test and Fisher's exact test was employed for inter group analysis of categorical data and for intra- group (before vs after) analysis of data categorical, McNemar's test was applied. The graphical representation of data was presented by means of bar graphs. A p-value of less than 0.05 was considered statistically significant.

The effects of test drug on subjective symptoms like dyspnea, sputum, cough, wheezing were significant in comparison to placebo (Tables 4-10).

There was no toxic effect of either test or control dug on safety parameters. So it became evident that the test drug has significant effect on most of the subjective and objective parameters of COPD with no toxic effects on safety parameters. Therefore, the test drug is safe, effective, economical and has wide pharmacological actions.

16. Conclusion

The test drug Unani formulation showed significant effect on subjective and objective parameters, which vindicated our hypothesis that the drug has effect in COPD. Hence, it may be concluded that the test drug has significant effect on subjective & objective parameters of COPD without having any toxic effect on any of the safety parameters. The sample size was small, so trials on larger sized samples needs to be carried out to furthur evaluate the efficacy of the drug on large scale. Therefore, the test drug is safe, effective, economical and has wide pharmacological actions.

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