EFFECT OF TINOSPORA CORDIFOLIA IN CHRONIC BRONCHITIS PATIENTS

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ABSTRACT

BACKGROUND

Chronic obstructive pulmonary disease is one of the common problem affecting 10% of population above the age of 45 years in the world, associated with frequent acute medical admissions to hospital. One of the factor contributing in incidences of repeated infections is suppressed immune response by host. The depression of immune system is characterised by a reduction in the number and phagocytic function of neutrophils and macrophages as well as a reduction in the intracellular bactericidal capacity of these cells. The T-cell function is also diminished. The potential of Indian medicinal plants to be useful as immunostimulants appears encouraging. Ayurveda, the Indian traditional system of medicine, lays emphasis on promotion of health a similar concept to strengthening host defense against different diseases. These plants are labelled as 'Rasayanas,' *Tinospora cordifolia* is one of them. Present study was undertaken by Department of Pharmacology, Clinical Division, Govt. Medical College and Hospital, Aurangabad to evaluate.

MATERIALS AND METHODS

Present study was randomised, single blind, placebo controlled study. A total of 60 patients were enrolled in the study, divided into two groups of 30 each. Number of episodes of acute exacerbations in previous two months were recorded. Chief complaints and history regarding present illness was asked. The severity of symptoms present at the time of enrollment was recorded independently in respect of each patient on a four-point scale (Absent, mild, moderate and severe). Film coated *Tinospora cordifolia* tablet contains 500 mg of active ingredient were provided to each patient of test group and identical looking placebo tablets to each patient of placebo group.

RESULTS

There is statistically significant ($P < 0.05$) increase in percentage of predicted values of FEV₁ and Peak Expiratory Flow in test group as compared to Placebo group. There was statistically significant ($P < 0.05$) reduction in episodes of acute exacerbations in Test group as compared to Placebo group. There was significant clinical improvement in Test group as compared to Placebo group. The *Tinospora cordifolia* group had better improvement in quality of life as compared to Placebo group.

CONCLUSION

Tinospora cordifolia reduces repeated infections, improves signs and symptoms, improves quality of life and also improve lung functions. So it can be given as adjuvant therapy in chronic bronchitis patients in addition to standard treatment.

KEYWORDS

Tinospora Cordifolia, Chronic Bronchitis.

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BACKGROUND

Chronic obstructive pulmonary disease is one of the common problem affecting 10% of population above the age of 45 years in the world.¹ This is associated with frequent acute medical admissions to hospital. These frequent acute exacerbations result in repeated hospitalisation, general disability and absence from work.

If properly not treated, patients may land into complications and contribute to significant morbidity and mortality.² There is evidence to suggest that morbidity and mortality rates in COPD patients are rising and as such prompt and proper treatment of these patients is essential.³

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One of the factor contributing in incidences of repeated infections is suppressed immune response by host. The depression of immune system is characterised by a reduction in the number and phagocytic function of neutrophils and macrophages as well as a reduction in the intracellular bactericidal capacity of these cells. The T-cell function is also diminished.⁴

An attempt to overcome this problem has been made by introducing the concept of 'prohost' therapy. Several naturally occurring and synthetic substances like BCG, *Corynebacterium parvum*, muramyl dipeptide, glucans, interleukin-1 and colony stimulating factors have been used to enhance the nonspecific host resistance against infections. However, these substances share several limitations, one of their major drawbacks is the necessity to administer them parenterally, another factor is the cost of the therapy.

Against this background, the potential of Indian medicinal plants to be useful as immunostimulants appears encouraging.⁵ Ayurveda, the Indian traditional system of medicine, lays emphasis on promotion of health a similar concept to strengthening host defense against different

diseases. These plants are labelled as 'Rasayanas,' *Tinospora cordifolia* is one of them.⁶

Tinospora cordifolia also known as Guduchi belongs to family menispermaceae.⁷ It is a large glabrous climber with succulent corks grooved stems. *Tinospora cordifolia* is claimed to be useful as a general tonic, diuretic, antipyretic, anti-inflammatory and aphrodisiac in Ayurveda.⁸ Thattai UM and Dahanukar SA 1989 demonstrated immunostimulatory effect of *Tinospora cordifolia*.⁴

Present study was undertaken by Department of Pharmacology, Clinical Division, Govt. Medical College and Hospital, Aurangabad to evaluate *Tinospora cordifolia*'s immunostimulatory effect in chronic bronchitis patients receiving standard drug therapy, parameters considered were-

- Reduction in episodes of acute exacerbations.
- Improvement in signs and symptoms clinically.
- Improvement in quality of life.

Aims and Objectives

1. To evaluate the efficacy of *Tinospora cordifolia* in improvement of signs and symptoms in patients with chronic bronchitis as an adjuvant to standard therapy.
2. To evaluate reduction in incidence of acute exacerbations in patients with chronic bronchitis by *Tinospora cordifolia* as an adjuvant to standard therapy.
3. To evaluate improvement in quality of life in patients with chronic bronchitis by *Tinospora cordifolia* as an adjuvant to standard therapy.
4. To evaluate improvement in pulmonary function test in patients with chronic bronchitis by *Tinospora cordifolia* as an adjuvant to standard therapy.

MATERIALS AND METHODS

Present study was conducted in Department of Pharmacology, Clinical Division, Government Medical College and Hospital, Aurangabad.

Study Design

Randomised, Single Blind, Placebo Controlled Study.

Study Population

Sample Size

Total 60 patients were enrolled in the study. These patients were randomly divided into two groups of 30 each.

Inclusion Criteria

Those included were diagnosed cases of chronic bronchitis between 18 to 70 years' age group.

Exclusion Criteria

Patients with complication like cor pulmonale and respiratory failure.

Study Plan

Patients were selected from O.P.D., Govt. Medical College and Hospital, Aurangabad. Patients were diagnosed as having chronic bronchitis and satisfying the inclusion criteria were enrolled in the study. After explaining all the details of study, actions and safety of drug, written consent was taken. Study was approved by Ethical Committee of Govt. Medical College and Hospital, Aurangabad. Patients were assigned to two

groups of 30 each, (either Test or Placebo). Patients were randomly divided into groups.

Name, age and address of each patient was noted on case record form; personal history like smoking and alcohol was noted. Weight, temperature and blood pressure were recorded. Number of episodes of acute exacerbations in previous two months were recorded. Chief complaints and history regarding present illness was asked.

Symptoms like breathlessness, cough and expectoration were asked. Physical examination pertaining to respiratory systems was done. The severity of symptoms present at the time of enrollment was recorded independently in respect of each patient on a four-point scale (Absent, mild, moderate and severe) with qualifying norms given below.

-	Absent	Symptoms Absent
+	Mild	Symptoms Present, but no Interference with Daily Activities
++	Moderate	Symptoms Present and Some Interference with Daily Activities
+++	Severe	Symptoms Present with Incapacitation

Also, total symptom score was arrived at by adding individual severity scores (each + mark was to be taken as 1 i.e. + = 1, ++ = 2, +++ = 3). On physical examination wheezing, respiratory sound and prolonged expiration was examined.

Investigations

The following baseline investigation was carried out prior to administration of study drugs.

1. Complete blood count.
2. Spirometry- Forced expiratory volume in 1 sec. (FEV-1), Peak Expiratory Flow (PEF).

Followup

Patients were followed up every 15 days. On each followup, drugs for next 15 days was given to patients. On each followup symptoms like cough, expectoration and breathlessness were asked. Physical examination was done.

Investigations like CBC and Spirometry was done at baseline after one month at the end of study.

Spirometry

Pulmonary function test was done on computerised Spirometry. Instrument used is called as spirometrics, which was made in USA.

Force Expiratory Volume in One Second (FEV)

FEV is performed during FVC maneuver.

Procedure

Patient is asked to take deep inspiration; as soon as inspiration ends patient has to expire completely into apparatus.

Amount of air expired in one second is considered as FEV₁, it is directly calculated by apparatus.

Peak Expiratory Flow Rates (PEFR)

PEFR is the maximum flow rate attainable any time during forced expiratory volume from the position of maximum inspiration.

Procedure

Nostrils were closed with clamp, patient was asked to take a deep breath and blow the air in flow meter as fast as possible, it was recorded in litres per second.

Quality of Life Assessment

Quality of life was assessed at the baseline and every 15 days. Following were the parameters assessed.

Able to Carry on Normal Activity and to Work, no Special Care is needed

- Normal, no complaints, no evidence of disease 100%.
- Able to carry on normal activity, minor signs or symptoms of disease 90%.
- Normal activity with effort, some signs and symptoms of disease 80%.

Unable to Work. Able to Live at Homecare for Most Personal Needs. A Varying amount of Assistance is needed

- Cares for self, unable to carry on normal activity or to do active work 70%.
- Requires occasional assistance, but is able to care for most of his needs 60%.
- Requires considerable assistance and frequent medical care 50%.

Unable to Care for Self. Requires Equivalent of Institutional or Hospital Care. Disease may be Progressing Rapidly

- Disabled, required special care and assistance 40%.
- Severely disabled, hospitalisation is indicated although death not imminent 30%.
- Very sick, hospitalisation necessary, active supportive treatment necessary 20%.

Moribund, fatal processes progressing rapidly 10%, Dead 0%.

Drug Administration

Tablets

- Film coated Tinospora cordifolia tablet contains 500 mg of active ingredient. Tablets were dispensed in bottle containing 50 tablets. Each bottle was for 15 days therapy. Such 4 bottles were provided to each patient of Test group.
- Palcebo tablets were identical looking packed in bottles. Each bottle contains 50 tablets. One bottle was provided for 15 days, such 4 bottles were provided to each patient of Palcebo group.

Dosage

Test Group

Tab. Tinospora cordifolia 500 mg three times a day for a period of 8 weeks from the bottle assigned to him/her.

Placebo Group

Placebo tablets three times a day for a period of 8 weeks from the bottle assigned to him/her.

Standard Therapy

Acute exacerbations were treated with antibiotics, (Roxithromycin 150 mg BD), Theophylline 200 mg BD and

Asthalin rotahaler. Therapy was given up to the control of condition. Additional therapy like higher antibiotics and steroid therapy was needed for some patients to control acute attack.

Evaluation

Efficacy

Efficacy was compared on the Basis of-

- Improvement in symptoms and sign judged by scoring every 15 days.
- Reduction in number of acute exacerbations during 8 weeks of study compared to previous 2 months.
- Improvement in quality of life judged by parameters mentioned.
- Improvement in pulmonary performance calculated by spirometry.

Safety

Safety of drug was recorded by noting side effects experienced by patients.

Statistical Analysis

Student's unpaired 't' test applied for comparison between results of placebo and test group.

Sl. No.	*Percentage of Prediction of Expected Value	
	Baseline	At the End of Study
1	27	50
2	16	33
3	31	45
4	25	30
5	18	25
6	30	41
7	15	24
8	17	25
9	36	43
10	27	40
11	25	33
12	32	47
13	27	50
14	30	50
15	31	45
16	31	47
17	50	65
18	27	26
19	30	42
20	32	46
21	45	58
22	42	51
23	25	38
24	32	46
25	35	48
26	45	56
27	40	53
28	20	21
29	26	35
30	39	48
Mean	30.2	42.36 ± 10.32

Table 1. Effect of Tinospora cordifolia on Force Expiratory Volume in 1 Sec. (FEV) of Spirometry in Test Group in Ch. Bronchitis Patients

*Expected values of spirometry was calculated by computerised spirometry machine on the basis of factors affecting it.

Sl. No.	*Percentage of Prediction of Expected Value	
	Baseline	At the End of Study
1	31	28
2	25	25
3	21	25
4	22	39
5	30	35
6	25	32
7	29	31
8	26	27
9	29	31
10	28	30
11	43	41
12	33	36
13	35	36
14	28	29
15	35	34
16	28	29
17	29	33
18	43	46
19	28	31
20	30	36
21	40	43
22	33	35
23	29	33
24	35	38
25	35	40
26	35	41
27	25	26
28	40	42
29	28	34
30	22	23
Mean	29.33	33.63 ± 5.73

Table 2. Effect of *Tinospora cordifolia* on Force Expiratory Volume in 1 sec. (FEV) of Spirometry in Test Group in Ch. Bronchitis Patients

*Expected values of spirometry was calculated by computerised spirometry machine on the basis of factors affecting it.

	Test Group	Placebo Group
Mean	42.36	33.63
S.D.	10.32	5.73
'T' value	4.05	
'P' value	*P < 0.05	

Table 3. Comparison of Force Expiratory Volume in 1 sec. (FEV) of Spirometry in Test and Placebo Group in Ch. Bronchitis Patients

*Statistically significant

Sl. No.	*Percentage of Prediction of Expected Value	
	Baseline	At the End of Study
1	14	31
2	20	28
3	22	36
4	16	22
5	11	19
6	23	32
7	13	20
8	22	30
9	19	25
10	15	26
11	16	23
12	25	38

13	18	31
14	13	31
15	20	36
16	22	37
17	37	47
18	15	15
19	20	30
20	25	36
21	34	44
22	22	36
23	25	36
24	25	36
25	31	41
26	32	41
27	25	31
28	16	18
29	18	32
30	27	34
Mean	21.36	30.7 ± 8.37

Table 4. Effect of *Tinospora cordifolia* on Peak Expiratory Flow (PEF) of Spirometry in Test Group in Chronic Bronchitis Patients

*Expected value values of spirometry was calculated by computerised spirometry machine on the basis of factors affecting it.

Sl. No.	*Percentage of Prediction of Expected Value	
	Baseline	At the End of Study
1	25	22
2	28	28
3	12	15
4	30	27
5	29	31
6	22	30
7	22	25
8	15	16
9	22	2
10	20	31
11	29	25
12	22	22
13	25	27
14	20	22
15	29	27
16	20	22
17	22	25
18	24	30
19	20	23
20	22	27
21	23	26
22	23	26
23	22	25
24	31	33
25	21	27
26	25	29
27	15	17
28	23	25
29	20	25
30	12	13
Mean	22.43	24.53 ± 4.58

Table 5. Effect of *Tinospora cordifolia* on Peak Expiratory Flow (PEF) of Spirometry in Test Group in Ch. Bronchitis Patients

*Expected values of spirometry was calculated by computerised spirometry machine on the basis of factors affecting it.

	Test Group	Placebo Group
Mean	30.70	24.53
S.D.	8.37	4.58
‘T’ value	3.54	
‘P’ value	*P < 0.05	
<i>Table 6. Comparison of Force Expiratory Volume in 1 sec. (FEV) of Spirometry in Test and Placebo Group in Ch. Bronchitis Patients</i>		

*Statistically significant

Sl. No.	Number of Episodes	
	Pretreatment*	During Treatment**
1	6	2
2	7	2
3	3	1
4	2	1
5	4	2
6	3	2
7	3	1
8	2	2
9	5	2
10	5	2
11	5	2
12	5	2
13	6	3
14	5	2
15	4	1
16	5	2
17	6	3
18	6	3
19	3	1
20	5	2
21	2	2
22	6	3
23	5	2
24	5	4
25	5	2
26	5	2
27	4	2
28	5	2
29	3	2
30	5	3
Mean	4.50	2.06±0.41
Table 7. Effect of <i>Tinospora cordifolia</i> on Peak Expiratory Flow (PEF) of Spirometry in Test Group in Ch. Bronchitis Patients		

*Episodes in previous two months before starting treatment.

**Episodes during two months of study.

Sl. No.	Number of Episodes	
	Pretreatment*	During Treatment**
1	6	4
2	5	4
3	5	4
4	4	4
5	3	3
6	4	4
7	5	4
8	3	4
9	5	4
10	4	4
11	3	3
12	3	4
13	4	4
14	5	4

15	6	5
16	3	3
17	3	3
18	3	4
19	4	4
20	3	2
21	5	4
22	4	4
23	5	5
24	5	4
25	5	4
26	4	4
27	6	4
28	4	4
29	5	4
30	6	5
Mean	4.33	3.9±0.79

Table 8. Effect of *Tinospora cordifolia* on Peak Expiratory Flow (PEF) of Spirometry in Test Group in Ch. Bronchitis Patients

*Episodes in previous two months before starting treatment.

**Episodes during two months of study.

	Test Group	Placebo Group
Mean	2.06	3.90
S.D.	0.41	0.76
'T' value	11.86	
'P' value	*P < 0.05	
Table 9. Comparison of Reduction in Incidence of Episodes of Acute Exacerbations in Test and Placebo Group in Ch. Bronchitis Patients		

*Statistically significant

Sl. No.	Percentage Score	
	Baseline	After 2 Months
1	0	75
2	0	50
3	25	75
4	0	75
5	25	75
6	0	75
7	0	75
8	0	75
9	0	75
10	0	75
11	0	50
12	0	50
13	0	50
14	25	75
15	0	75
16	0	75
17	0	50
18	0	25
19	0	75
20	0	75
21	25	75
22	0	75
23	0	75
24	0	75
25	0	75
26	0	50
27	0	50
28	0	25
29	0	50
30	0	75

Mean	3.33	65±15.27
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Table 10. Effect of *Tinospora cordifolia* on Peak Expiratory Flow (PEF) of Spirometry in Test Group in Ch. Bronchitis Patients

Sl. No.	Percentage Score	
	Baseline	After 2 Months
1	0	25
2	0	25
3	0	25
4	0	50
5	0	0
6	0	25
7	0	25
8	0	25
9	0	25
10	25	25
11	0	25
12	0	25
13	0	25
14	0	25
15	0	0
16	0	25
17	0	25
18	0	25
19	0	25
20	25	75
21	0	50
22	25	25
23	0	25
24	0	50
25	0	25
26	25	25
27	0	50
28	0	25
29	25	50
30	0	25
Mean	4.16	29.16±14.55

Table 11. Effect of *Tinospora cordifolia* on Peak Expiratory Flow (PEF) of Spirometry in Test Group in Ch. Bronchitis Patients

	Test Group	Placebo Group
Mean	65.00	29.16
S.D.	15.27	14.55
'T' value	9.30	
'P' value	*P<0.05	

Table 12. Comparison of Clinical Assessment in Test and Placebo Group in Ch. Bronchitis Patients

*Statistically significant

Sl. No.	Percentage Score	
	Baseline	After 2 Months
1	50	90
2	50	80
3	60	90
4	50	90
5	60	90
6	70	90
7	50	80
8	70	90
9	60	90
10	50	80

11	50	80
12	50	80
13	70	90
14	60	90
15	70	90
16	50	90
17	50	80
18	40	50
19	60	90
20	50	80
21	50	80
22	50	80
23	50	70
24	50	80
25	50	80
26	50	80
27	50	80
28	50	60
29	50	70
30	50	70
Mean	51.66	81.33 ± 9.56

Table 13. Assessment of Effect of *Tinospora cordifolia* on Quality of Life in Test Group in Ch. Bronchitis

Sl. No.	Percentage Score	
	Baseline	After 2 Months
1	60	70
2	70	80
3	70	80
4	50	60
5	50	70
6	40	60
7	40	50
8	40	50
9	50	60
10	50	70
11	50	70
12	50	60
13	50	60
14	50	60
15	50	50
16	50	60
17	50	60
18	50	60
19	50	60
20	50	80
21	50	60
22	50	60
23	50	60
24	50	60
25	50	60
26	50	60
27	50	80
28	50	60
29	50	70
30	50	60
Mean	50.66	63±8.22

Table 14. Assessment of Effect of *Tinospora cordifolia* on Quality of Life in Placebo Group in Ch. Bronchitis Patients

	Test Group	Placebo Group
Mean	81.33	63.00
S.D.	9.56	8.22
‘T’ value	7.96	
‘P’ value	*P < 0.05	
Table 15. Comparison of Quality of Life in Test and Placebo Group in Ch. Bronchitis Patients		

*Statistically significant

RESULTS

Table 1, 2, 3

Shows effect of *Tinospora Cordifolia* on Force Expiratory Volume in one sec, of spirometry in test and placebo group in chronic bronchitis patients. There is statistically significant ($P < 0.05$) increase in percentage of predicted values in test group as compared to Placebo group.

Table 4, 5, 6

Shows effect of *Tinospora cordifolia* on Peak Expiratory Flow of Spirometry in Test and Placebo group in chronic bronchitis patients. There is statistically significant ($P < 0.05$) increase in percentage of prediction values in Test group as compared to Placebo group.

Table 7, 8, 9

Shows effect of *Tinospora cordifolia* on reduction of episodes of acute exacerbations in Test and Placebo group. There is statistically significant ($P < 0.05$) reduction in episodes of acute exacerbations in Test group as compared to Placebo group.

Table 10, 11, 12

Shows effect of *Tinospora cordifolia* on clinical improvement in Test and Placebo group. There is statistically significant ($P < 0.05$) improvement clinically in Test group as compared to Placebo group.

Table 13, 14, 15

Shows effect of *Tinospora cordifolia* on quality of life in test and placebo group. There is statistically significant ($P < 0.05$) improvement in quality of life Test group as compared to Placebo group.

DISCUSSION

A number of plants and formulations have been reported in Ayurveda for their use in treatment of immune deficiency diseases in the last 2 or 3 decades.⁹ Some of them have been screened and tested for their efficiency. The results of such experimental works have revealed a clear picture of pharmacological activity.^{10,11} *Tinospora cordifolia* has been evaluated for its activity and found to possess potent immunomodulatory activity by various workers.^{12,13}

Thatte U M showed *Tinospora cordifolia* has been found to induce leukocytosis,^{14,15} improve phagocytosis and intracellular killing capacity of neutrophils^{16,17} and macrophages.¹⁸ Dahanukar S A and Thatte U M demonstrated *Tinospora cordifolia* induces T-lymphocyte proliferation and increases cytokine secretion, such as interleukin-1 and interleukin-2 and Granulocyte Macrophage-Colony

Stimulating Factor (GM-CSF).¹⁹ Sainis K B showed that T.C. contains polyclonal B. cell activators when resulted in B-lymphocytes proliferation and Mathew et al demonstrated enhanced antibody synthesis.

Kapil A and Sharma S demonstrated anticomplementary activity and serum opsonising activity.

Tinospora cordifolia extensively studied in patients with obstructive jaundice, cirrhosis, H. pylori infection, pulmonary tuberculosis, chronic asthma, abdominal sepsis and K. pneumonia injection. It has given better results in the form of early improvement, reduction in repeated infection and prevention of complications.

In present study when *Tinospora cordifolia* was studied in chronic bronchitis patients, results obtained showed improvement in symptoms like breathlessness, cough, expectoration and wheeze in Test group as compared to Placebo group, which was statistically significant ($P < 0.05$).

When quality of life was compared in Test and Placebo group in the form of - 1) Whether able to carry out normal activity and no special care is needed, 2) Able to live at home with assistance and 3) Unable to care for self and requires hospital care. Results showed improvement in quality of life in Test group statistically significant as compared to Placebo group ($P < 0.05$). Above results are in consistent with studies of previous workers.

In the study, incidence of episodes of acute exacerbations during study was compared with episodes of acute exacerbations in previous two months before starting study. Results indicate statistically significant reduction in incidence of episodes of acute exacerbations in Test group as compared to Placebo group ($P < 0.05$).

When values of Pulmonary Function Test in the form of Forced Expiratory Volume in one second (FEV-1) and Peak Expiratory Flow (PEF) were compared, there was statistically significant increase in Test group as compared to Placebo group. Though statistically significant increase in value of FEV-1 and PEF were there, values did not reach the normal levels as airway obstruction in chronic bronchitis remain irreversible. This rise may be due to anti-inflammatory action, reduction in episodes of exacerbation and increased alveolar macrophage function by *Tinospora cordifolia*. *Tinospora cordifolia* was well tolerated and no side effects were reported.

CONCLUSION

To conclude in present study, *Tinospora cordifolia* reduces repeated infections, improves signs and symptoms, improves quality of life and also improve lung functions. So it can be given as adjuvant therapy in chronic bronchitis patients in addition to standard treatment.

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