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A Randomized Study of Effect of Tinospora Cordifolia in Chronic Bronchitis Patients

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Abstract
Introduction: *Chronic Bronchitis (CB) is defined as a chronic cough and sputum production for at least 3 months a year for 2 consecutive years. [3] It is covered under the umbrella term of Chronic Obstructive Pulmonary Disease (COPD).*
Material and Methods: *Randomized, Single Blind, Placebo Controlled Study was conducted in the M.G.M Medical College, Jamshedpur, Jharkhand. In this study 100 patients were enrolled. These patients were randomly divided into two groups of 50 each. Chronic bronchitis patients between 18 to 70 years age group were included in this study. Patients with complications of respiratory failure were excluded from the study.*
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.*
Key words: *Tinospora cordifolia, Chronic Obstructive Pulmonary Disease, Chronic Bronchitis*

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I. Introduction

Tinospora cordifolia (Willd.) Miers. (Menispermaceae) is a large, glabrous, climbing shrub. It is widely used in veterinary folk medicine/Indian system of medicine (Ayurvedic) for its general tonic, antispasmodic, antiinflammatory, anti-arthritic, and antidiabetic properties. The antioxidant, antidiabetic, anti-inflammatory and immunomodulatory properties of novel polysaccharide and glucans from T. cordifolia have also been well documented (Nair et al., 2006; Pendse et al., 1981; Prince et al., 2004; Singh et al., 2003).

Chronic Bronchitis (CB) is defined as a chronic cough and sputum production for at least 3 months a year for 2 consecutive years. [3] It is covered under the umbrella term of Chronic Obstructive Pulmonary Disease (COPD). The COPD spectrum ranges from Emphysema to Chronic Bronchitis and it occurs when the airways become inflamed and the air sacs in your lungs are damaged. Emphysema occurs when your alveolar membrane breaks down whereas CB is the inflammation and excessive mucus build-up in your bronchi.[4] Many patients have characteristics of both, putting them somewhere along the spectrum.

II. Material And Methods

Randomized, Single Blind, Placebo Controlled Study was conducted in M.G.M Medical College, Jamshedpur, Jharkhand. In this study 100 patients were enrolled. These patients were randomly divided into two groups of 50 each. Chronic bronchitis patients between 18 to 70 years age group were included in this study. Patients with complications of respiratory failure were excluded from the study. 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.

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-I), Peak Expiratory Flow (PEF).

Follow up: 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 FEVh, 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 i. Normal, no complaints, no evidence of disease 100%.
ii. Able to carry on normal activity, minor signs or symptoms of disease 90%.
iii. 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
i. Cares for self, unable to carry on normal activity or to do active work 70%.
ii. ii. Requires occasional assistance, but is able to care for most of his needs 60%.
iii. iii. 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
i. Disabled, required special care and assistance 40%.
ii. Severely disabled, hospitalisation is indicated although death not imminent 30%.
iii. Very sick, hospitalisation necessary, active supportive treatment necessary 20%.

Moribund, fatal processes progressing rapidly 10%, Dead 0%.
Drug Administration
Tablets: a. 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.
b. 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
i. Improvement in symptoms and sign judged by scoring every 15 days.
ii. Reduction in number of acute exacerbations during 8 weeks of study compared to previous 2 months.
iii. Improvement in quality of life judged by parameters mentioned.
iv. 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.

III. Results

SI.NO	Percentage of prediction of expected value	
	Baseline	**At the end of the study**
1	39	48
2	26	35
3	40	53
4	45	56
5	43	45
6	46	47
7	42	46
8	40	43
9	38	41
10	39	37
11	27	50
12	29	52
13	26	45
14	29	48
15	32	39
16	39	48
17	26	35
18	40	53
19	45	56
20	43	45
21	46	47
22	42	46
23	40	43
24	38	41
25	39	37
26	27	50
27	29	52
28	26	45
29	29	48
30	32	39
31	39	48
32	26	35
33	40	53
34	45	56
35	43	45
36	46	47
37	42	46
38	40	43
39	38	41
40	39	37
41	27	50
42	29	52
43	26	45
44	29	48
45	32	39
46	26	35
47	40	53
48	45	56
49	43	45
50	46	47
Mean	29.77	34.56±6.54

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

SI.NO	Percentage of prediction of expected value	
	Baseline	**At the end of the study**
1	27	50
2	29	52
3	26	45
4	29	48
5	32	39
6	39	48
7	26	35
8	40	53
9	45	56
10	43	45

11	46	47
12	42	46
13	40	43
14	38	41
15	39	37
16	27	50
17	29	52
18	26	45
19	29	48
20	32	39
21	39	48
22	26	35
23	40	53
24	45	56
25	43	45
26	46	47
27	42	46
28	40	43
29	38	41
30	39	37
31	27	50
32	29	52
33	26	45
34	29	48
35	32	39
36	26	35
37	40	53
38	45	56
39	43	45
40	46	47
41	27	50
42	29	52
43	26	45
44	29	48
45	32	39
46	39	48
47	26	35
48	40	53
49	45	56
50	43	45
Mean	30.5	45.32±8.54

Table 2: Effect of Tinospora cordifolia on Force Expiratory Volume in 1 Sec. (FEV) of Spirometry in Placebo Group in Ch. Bronchitis Patients.

SI.NO	**Percentage Score**	
	Baseline	**After 2 Months**
1	60	90
2	50	80
3	70	70
4	40	60
5	60	90
6	50	80
7	40	70
8	70	60
9	40	90
10	70	80
11	60	90
12	60	90
13	50	80
14	70	70
15	40	60
16	60	90
17	50	80
18	40	70
19	70	60
20	40	90
21	70	80
22	60	90
23	60	90
24	50	80

25	70	70
26	40	60
27	60	90
28	50	80
29	40	70
30	70	60
31	60	90
32	50	80
33	70	70
34	40	60
35	60	90
36	50	80
37	40	70
38	70	60
39	40	90
40	70	80
41	60	90
42	60	90
43	50	80
44	70	70
45	40	60
46	60	90
47	50	80
48	40	70
49	70	60
50	40	90
Mean	52.66	64.23±6.22

Table 3: Effect of Tinospora cordifolia on quality of life in Test Group in Ch. Bronchitis Patients

SI.NO	**Percentage Score**	
	Baseline	**After 2 Months**
1	60	90
2	50	80
3	70	70
4	40	60
5	60	90
6	50	80
7	40	70
8	70	60
9	40	90
10	70	80
11	60	90
12	60	90
13	50	80
14	70	70
15	40	60
16	60	90
17	50	80
18	40	70
19	70	60
20	60	90
21	50	80
22	70	70
23	40	60
24	60	90
25	50	80
26	40	70
27	70	60
28	40	90
29	70	80
30	60	90
31	60	90
32	50	80
33	70	70
34	40	60
35	60	90
36	50	80
37	40	70
38	70	60
39	40	90

40	60	90
41	50	80
42	70	70
43	40	60
44	60	90
45	50	80
46	40	70
47	70	60
48	40	90
49	70	80
50	60	90
Mean	50.77	62.35±8.22

Table 4: Effect of Tinospora cordifolia on quality of life in placebo Group in Ch. Bronchitis Patients

IV. Discussion

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 wheezing 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 ($P < 0.05$).

V. 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.

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