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A Clinical Study to Evaluate the Effect of Certain Ayurvedic Formulations in the Management of *Shwasa Roga* w.s.r. to Chronic Obstructive Pulmonary Disease (COPD)

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ABSTRACT

Background: Chronic obstructive pulmonary disease (COPD) is emerging as a leading cause of death worldwide. It is a disease of old age but genetics and exposure to smoke and fumes of various kinds also make one prone for the development of this disease. In modern medicine various treatment protocols are mentioned but they often have serious side effects. Moreover, this disease has a heterogeneous pattern which means that there are different presentations and different responses to the therapies. So, it is a matter of concern to the scientific world to carry out research works to understand this disease fully and to devise better treatment protocols for the disease. Chronic obstructive pulmonary disease is having similar signs and symptomatology as *Shwasa roga* described in the *Ayurvedic* texts. A clinical trial was conducted on 20 patients at R.G.G.P.G. Ayurvedic College Paprola by using classic *Ayurvedic* formulations namely *Kantakari avaleha, Shringyadi churna, Guduchyadi kwatha and Kulathadi kwatha* in syrup form. Patients were alternatively divided into two groups of 10 patients each. The *Ayurvedic* formulations have shown beneficial effects by virtue of their bronchodilator, mucolytic, anti-inflammatory actions for the alleviation of symptoms in the patients of COPD with no untoward effects.

Key words: *Shwasa roga*, chronic obstructive pulmonary disease, COPD, *Kantakari Avaleha, Shringyadi Churna, Guduchyadi Kwatha, Kulathadi Kwatha*.

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INTRODUCTION

Shwasa roga is considered as one of the most dreadful diseases as described in *Ayurvedic* texts. *Shwasa roga* is a disease of the *Pranavaha strotasa* (Tracheobronchial tree). In this disease *Prana vayu* gets vitiated and gets obstructed by the vitiated *Kapha* which hinders its natural path and forces it to move in the opposite direction i.e., upwards and thus unable to perform normal functions. [1] In modern science similar symptomatology is also found in Chronic Obstructive Pulmonary Disease (COPD). COPD is defined by the presence of airways obstruction, which does not change markedly over several months and is not fully reversible [2]. It is a chronic, ongoing, progressive disease of the lower respiratory tract in the lungs. Tobacco smoking is the most common cause of COPD, with factors such as air pollution and genetics playing smaller role. The most common symptoms of COPD are sputum production, shortness of breath and productive cough. These symptoms are present for a prolonged period and typically worsen over time. COPD is a heterogeneous condition embracing several overlapping pathological processes including Chronic bronchitis (A productive cough that is present for at least three months for two consecutive years) and Emphysema**.** Many patients also exhibit a systemic component characterized by impaired nutrition, weight loss and skeletal muscle dysfunction. The Global Burden of Disease Study reports a prevalence of 251million cases of COPD globally in 2016. [3]. Complications of the disease are life threatening and ends in repeated exacerbations, respiratory failure and end of life. In modern medicine, various researches have been conducted and many are still in progress. They are usually associated with side effects such as gastrointestinal issues, weight loss, sleep and mood disturbances. In *Ayurvedic* texts the disease is due to vitiation of *Vata* and *Kapha dosha* which then leads to symptoms of *Shwasa roga* (Bronchial Asthma). So, the present research work was thus designed to assess the efficacy and side effects (if any) of the formulations which have primarily *Vata kapha shamaka* and *Vata anulomana* (downward movement) properties without least or no untoward effects in the management of *Shwasa roga* .

MATERIAL AND METHOD

The patients of COPD fulfilling the diagnostic criteria were selected from the OPD and IPD Department of Kayachikitsa of R.G.G.P.G. Ayurvedic College and Hospital, Paprola, Distt .Kangra (H.P.). The trial drugs were prepared at the college pharmacy after getting approval from the Drug Approval Committee. Before the commencement of trial approval was taken from the Institutional Ethics Committee vide batch no. Ayu/IEC/2016/1106 on 10/08/2017.

Inclusion criteria

Patients willing for trial, fulfilling the criteria of diagnosis and aged between 40 -80years of either gender.

Exclusion criteria

Patients not willing for trial, suffering from major systemic illness, poorly controlled hypertensive and diabetic patients, patients with advanced Type II respiratory failure and patients below 40 and above 80 years of age.

Selection and preparation of trial drugs

The present clinical trial included four formulations with various ingredients. Drugs were carefully chosen to pacify the involved *dosha* i.e. *Vata* and *Kapha* predominantly. The drugs have *Ushana virya* (hot potency) and *Vatanulomana* (downward movement) properties. Due to this they have potent action in alleviating the symptoms of *Shwasa roga*..

Reference of *Shringyadi churna with anupana(*vehicle*), of Guduchyadi kwatha* and *Kulathadi kwatha* (which was made in syrup form) has been taken from *Chakradatta* [4] and *Kantakari avaleha* has been taken from *Sharangdhar samhita.* [5]

All the formulations were prepared at college pharmacy of R.G.G.P.G. Ayu. College, Paprola.

Intervention

All the patients fulfilling the criteria of diagnosis and inclusion were randomly divided into two groups named as Trial Group-I and Trial Group-II.

Trial Group-I: Ten patients were given *Shringyadi churna* 3g twice a day with *anupana* of *Guduchyadi kwatha* and *Kantakari avaleha* 10g twice a day with luke warm water for 8 weeks.

Trial Group-II: Ten patients were given *Shringyadi churna* 3g twice a day with *anupana* of *Guduchyadi kwatha, Kantakari avaleha* 10g twice a day with luke warm water and *Kulathadi kwatha* in syrup form 10ml thrice a day for 8 weeks.

Contents of *Shringyadi churna:* *Karkatshringi (Pistacia integerrima), Shunthi(Zinziber officinale), Pippali(Piper longum), Nagarmotha, (Cyperus rotundus)Kachoora (Curcuma zedoaria), Maricha (Piper nigrum), Pushkarmula(Inula racemose)* and *Sarkara(sugar)* taken in equal amount.

Contents of *Guduchyadi kwatha:* *Vasa (Adhathoda vesica), Guduchi (Tinosporia cordifolia), Brihat panchmula.*

Contents of *Kantakari avaleha:*
Kantakari (Solanum surattense)
Guduci (Tinospora cordifolia)
Cavya (Piper chaba)
Citraka (Plumbago zeylanica)
Musta (Cyperus rotundus)
Karkatasrrigi
Sunthi (Zingiber officinale)
Marica (Piper nigrum)
Pippali (Piper longum)
Dhanvayasaka (Fagonia Arabica)
*Til Taila(*Sesame oil), *Madhu(Honey), Ghrita, Sarkara(Sugar),* Water for decoction.

Contents of *Kulathadi kwatha* in Syrup form: *Kulatha (Dolichos biflorus), Vasa (Adhathoda vesica) Shunthi ((Zingiber officinale), Kantakari (Solanum surattense) Pushkarmula (Inula racemose),*Sugar*(Sharkara)* and excipients.

Gradation of Subjective and Functional Symptoms (Subjective parameters) [6]

S. No.	Criteria	Grade 0	Grade 1	Grade 2	Grade 3	Grade 4
1.	Breathlessness	No dyspnea	Dyspnea on prolonged and heavy exertion	Dyspnea on moderate exertion	Dyspnea on mild exertion	Dyspnea even at rest
2.	Cough	No cough	Episodic (twice) in a day ;without much exhaustion	Episodic(three or four times) in a day; without much exhaustion	Most of the time in a day with exhaustion	Throughout the day with marked exhaustion
3.	Expectoration	Less than 5ml	5 to 10ml; thin	10 to 20ml; thin	25 to 50ml ;thick	50 to 100 ml; tenacious
4.	Wheezes	Not present	Occasionally ;twice in 24 hours	3-4 times in 24 hours	5-6 times in 24 hours	Throughout the day
5.	Heaviness of chest	No heaviness	Mild with wheezing occasionally	Mild relieved by expectoration	Moderate relieved by expectoration	Severe and wheeze remain throughout the day.
6.	Edema	Not present	Only mild pedal edema	Present on pedal and pretibial region	Present over lower limb(Pedal, Pretibial, Sacral)	Present all over the body
7.	Cyanosis	No cyanosis	Mild peripheral	Mild mixed	Moderate mixed	Gross mixed
8.	Intervention with allopathic drugs	No allopathic drug required	Required occasionally	Required regularly once daily	Required twice daily	Required more than twice a day
9.	Sleep pattern	Sleep in any posture comfortably (6-8 hours)	Sleep in any posture but disturbed	Sleep in propped up position(4-6hours)	Sleep in sitting posture(1-2hours)	Cannot sleep in any posture
10.	Pulse rate	70 to79 per minute	80 to 89 per minute	90 to 99 per minute	100 to 109 per minute	Over 110 per minute

Assessment of the results

After the completion of trial, the assessment of improvement was done on the basis of improvement in above said subjective and functional symptoms as well as on the basis of spirometry $FEV_{1(L)}$

Criteria for assessment [7]

All the patients were assessed for relief in signs and symptoms and objective parameters after the completion of trial. >10%

Categories	Subjective Criteria	Objective Criteria
Markedly improved	improvement over its pretrial value	>10% improvement in FEV_1 over its pretrial value
Improved	20-39% improvement	1-10% improvement in FEV_1
Not improved	<20% improvement	<1%or no change in FEV_1

Questionnaires: Improvement in the scores of the following questionnaires;

- St. George respiratory questionnaire [8]
- COPD assessment test [9]

Statistical analysis:

Paired and unpaired "t"-test were used for the statistical analysis of the observations and results.

Observations

Out of 20 patients 16 patients completed the trial(7 from Group I and 9 from Group II).Most of the patients were in the age group of 60-70 years(55%) ,and male (95%), married(100%),belonging to rural areas(100%),Hindu(100%),middleclass(55%), illiterate or educated only up to primary level(70%),farmers(60%),smokers(75%) and habitual to alcohol also(30%),having mixed diet(80%),average life style(95%),having insomnia(65%) and *Vataja prakriti*(50%).

Symptoms of COPD like breathlessness (100%), cough with varying levels of expectoration (100%), chest tightness (95%), edema (60%) and wheezing (80%) were present. On examination, cyanosis of varying degrees was present in 70% patients and had predominantly emphysema (40%), bronchitis (35%) and mixed pattern (25%).

RESULT

The therapy showed statistically significant effects on symptoms like breathlessness, cough and expectoration in both the groups. For other symptoms like heaviness of chest the effect was statistically significant in Group II and for wheeze the effect was statistically significant in Group I. There was statistically significant effect on edema in Group I while no significant change was observed for cyanosis in both groups (Table-1). Reduction was observed in need to use allopathic drugs. The change was statistically insignificant in Group I and statistically significant in Group II(p-value<0.001). The effect of therapy on sleep pattern was statistically insignificant for both the groups. (p-

value >0.05). The mean grade of pulse rate lowered down in both the groups. The change was statistically insignificant for Group I(p-value>0.05) and statistically significant for Group II(p-value<0.05) (Table-3). The difference was statistically highly significant (p<0.001) in both the groups for FEV_1(Table-5) Statistically significant result was observed for PEFR in Group II (p-value <0.05) while it was statistically insignificant in Group I (p-value >0.05) (Table-6). The difference was statistically significant in both the groups(p-value<0.05) for peripheral oxygen saturation (SPO_2) (Table-7). Scores of both the questionnaires i.e. the St. George Respiratory Questionnaire (SGRQ) and COPD assessment test (CAT) showed improvement. The change was statistically significant for both questionnaires in both groups (p-value <0.001) (Table-9,10). No significant changes were observed in the hematological investigations (Table-11)

Table no. 1- Subjective criteria

Sr. no	Category		Mean		% change	Std. Dev.		Std. Error		't'-value	'p'-value
			BT	AT		BT	AT	BT	AT		
1.	Breathlessness	Group I	2.571	1.714	33.33%	0.535	0.756	0.202	0.286	6.000	<0.001
		Group II	2.22	1.55	30.18%	0.667	0.726	0.222	0.242	4.000	0.004
2.	Cough	Group I	1.857	1.143	38.44%	0.900	0.690	0.340	0.261	3.873	0.008
		Group II	2.000	0.444	77.8%	0.707	0.527	0.236	0.176	8.854	<0.001
3.	Expectoration	Group I	1.143	0.429	62.46%	0.690	0.787	0.261	0.297	3.873	0.008
		Group II	1.333	0.222	83.34%	0.707	0.441	0.236	0.147	4.264	0.003
4.	Heaviness of chest	Group I	2.429	1.857	23.54%	0.787	0.690	0.297	0.261	1.922	0.103
		Group II	2.222	1.111	50%	1.202	1.054	0.401	0.351	4.264	0.003
5.	Wheeze	Group I	1.571	0.714	54.55%	1.134	0.951	0.429	0.360	6.000	<0.001
		Group II	1.000	0.222	77.8%	1.225	0.441	0.408	0.147	2.401	0.043
6.	Edema	Group I	0.429	0.143	66.67%	0.535	0.378	0.202	0.143	1.549	0.172
		Group II	1.111	0.000	100%	0.928	0.000	0.309	0.000	3.592	0.007
7.	Cyanosis	Group I	1.000	0.429	57.1%	0.816	0.535	0.309	0.202	1.549	0.030
		Group II	0.889	0.222	75.02%	0.928	0.441	0.309	0.147	1.947	0.022

Table no. 2- Effect of therapy on Subjective criteria

Sr.No.	Results	No. of patients		Percentage
		Group I	Group II	
1	Markedly improved	06	09	93.75%
2	Moderately improved	00	00	0%
3	Not improved	01	00	6.25%

Table no. 3- Functional criteria

Sr. no	Variables	Mean Score			% change	Std. Dev.		Std. Error		't'-value	'p'-value
			BT	AT		BT	AT	BT	AT		
1.	Intervention with allopathic drugs	Group I	1.857	1.571	15.40%	0.378	0.535	0.143	0.202	1.549	0.172
		Group II	2.222	1.222	45%	0.441	0.667	0.147	0.222	6.000	<0.001
2.	Sleep pattern	Group I	0.857	0.857	0%	0.378	0.378	0.143	0.143	0.000	1.000
		Group II	0.889	0.556	37.04%	0.601	0.527	0.200	0.176	2.000	0.081
3.	Pulse rate	Group I	1.286	0.857	33.35%	1.113	0.690	0.421	0.261	2.121	0.078
		Group II	1.556	1.111	28.59%	0.882	0.782	0.294	0.261	2.530	0.035

Table no.4-Effect of therapy on Functional criteria

Sr.No.	Results	No. of patients		Percentage
		Group I	Group II	
1	Markedly improved	01	05	37.5%
2	Moderately improved	03	03	37.5%
3	Not improved	03	01	25%

On Objective criteria:

Table no. 5-Forced expiratory volume in 1 second (FEV1)

Criteria	Mean Score		% relief	S.D.		S.E.		't' Value	'p'-value
	BT	AT		BT	AT	BT	AT		
Group I	103.714	13.143	9.09%	55.41	55.19	20.94	20.86	6.000	<0.001
Group II	177.0	194.2	9.71%	145.29	147.55	48.43	49.18	-5.494	<0.001

Table no.6-Peak expiratory flow rate (PEFR)

	Mean Score		% relief	S.D.		S.E.		't' Value	'p'-value
	BT	AT		BT	AT	BT	AT		
Group I	1.041	1.126	8.16%	0.37	0.32	0.141	0.121	1.772	0.127
Group II	1.17	1.33	13.67%	0.66	0.70	0.22	0.23	3.314	0.011

Table no. 7- Peripheral capillary oxygen saturation (SPO2)

	Mean Score		% relief	S.D.		S.E.		't' value	'p'-value
	BT	AT		BT	AT	BT	AT		
Group I	92.14	93.00	0.93%	2.34	2.44	20.94	20.86	-2.521	0.045
Group II	91.55	93.11	1.7%	4.19	3.94	1.39	1.31	3.776	0.005

Table no. 8- Effect of therapy on Objective parameter (FEV_1)

Sr. No.	Results	No. of patients		Percentage
		Group I	Group II	
1	Markedly improved	04	05	56.25%
2	Improved	01	02	18.75%
3	Not improved	02	02	25%

Questionnaires

Table no. 9- St. George Respiratory Questionnaire (SGRQ)

	Mean Score		% relief	S.D.		S.E.		't'- value	'p'-value
	BT	AT		BT	AT	BT	AT		
Group I	45.97	33.96	26.13%	12.57	10.22	4.7	3.8	10.762	<0.001
Group II	42.33	28.83	31.89%	10.38	4.41	3.46	1.47	5.526	<0.001

Table no. 10- COPD Assessment Test (CAT)

	Mean Score		% relief	S.D.		S.E.		't'-value	'p'-value
	BT	AT		BT	AT	BT	AT		
Group I	22.14	18.14	18.06%	6.51	5.17	2.4	1.9	5.527	0.001
Group II	21.44	12.77	40.45%	6.61	4.41	2.20	1.47	8.024	<0.001

Table no. 11-On Hematological profile:

Sr.no.	Category		Mean		% change	Std. Dev.		Std. Error		't'-value	'p' value
			BT	AT		BT	AT	BT	AT		
1.	Hb	Group I	13.08	12.54	4.12%	1.7	1.5	0.6	0.5	1.353	0.225
		Group II	13.27	13.31	0.3%	1.11	1.28	0.37	0.43	-0.125	0.904
2.	TLC	Group I	8557.1	8471.4	1.00%	1552.26	2324.01	586.7	878.7	0.106	0.919
		Group II	8955.56	8000.0	10.67%	3297.01	1773.41	1009.0	591.13	0.817	0.438
3.	ESR	Group I	29.57	28.57	3.38%	23.48	20.57	8.87	7.89	0.0815	0.938
		Group II	31.00	36.88	18.96%	21.98	38.95	7.32	12.98	-0.504	0.628

DISCUSSION

On Demographic Data

In the present study,20 patients fulfilling the inclusion criteria were enrolled for the study.

- Analysis of age wise distribution showed that maximum number of patients i.e. 55% were in the age group of 60-70 years and 95% patients were of male gender. Age factor plays a vital role in the disease as this disease is uncommon before the age of 40 years. This can be attributed to the fact that it takes several years to develop COPD.
- All the patients belonged to rural area as the place of study is located in a village. This disease is common in such people because of more use of domestic fuels and less awareness for health.
- Most of the enrolled patients were farmers. Hard manual work in farms and exposure to various types of dust made them prone to develop the disease.
- Majority of patients i.e.75% were chronic smokers while 30% patients were habitual to alcohol intake also. Smoking has been recognized as the most important causative factor for the development and progression of this disease. Passive exposure to cigarette/bidi smoke may also contribute to the development of COPD. More alcohol intake has been linked to more lung injury due to depletion of lung protecting-Glutathione.
- Maximum number of patients i.e.50% were of *Vataja prakriti* followed by 35% patients of *Kaphaja prakriti*. *Prakriti parikshana* (assessment of body constitution.*)* helps in diagnosis and to ascertain the prognosis of disease. In this disease there is *Vatakapha* vitiation and similar *Prakriti* of the patient goes in favor of the disease.
- 40% patients had predominantly emphysema followed by predominantly bronchitis in 35% patients.25% patients had mixed pattern.

On Investigation Data-

- **Hematology:** After the completion of trial changes were observed in all the three parameters of hematological investigation viz. Hemoglobin, Total leukocyte count and ESR. Hemoglobin has been suggested as easily and inexpensively measured prognostic indicator for COPD [10]. Leukocytes are markers of inflammation. The WBC count is associated with COPD severity and a risk factor for poor lung function and quality of life. Erythrocyte sedimentation rate provides as an inexpensive method to estimate the inflammatory process. Though the change was statistically insignificant (p-value <0.05), symptomatic improvement was there by which it can be assumed that the trial drugs possessed mild anti-inflammatory properties and also help to maintain hemoglobin at an optimum level.
- **Spiro metric parameters:** Spirometry is a standard respiratory function test for detection of COPD. It is a safe and practical procedure. FEV_1 is used to ascertain the severity of the disease while PEF measures the highest forced expiratory flow [11]. The test results as a percent of the predicted value for patient's height, age, gender, race and weight. There was a statistically significant change for both of these parameters in both the trial groups which indicates that the therapy has decreased the obstruction by clearing the channels of secretions by virtue of its expectorant, bronchodilator and anti-inflammatory properties.
- **Pulse oximetry:** Pulse oximetry is a non-invasive method for monitoring person's oxygen saturation. Statistically significant improvement was observed after the completion of trial. The therapy had resulted in relieving the channels of obstruction facilitating better air flow [12].

On Questionnaires-

Among patients with COPD, a baseline SGRQ score is a significant predictor of exacerbations, hospital admissions and death [13]. The COPD assessment test (CAT) is a validated test for evaluation of COPD impact on health status. The relationship between CAT score and FEV_1% predicted suggests that CAT is linked to the severity of airflow limitation and GOLD classification in stable COPD patients [14]. The change in the scores of both the questionnaires was statistically significant in both the groups.

Overall effect of therapy

In the present study,20 patients fulfilling the inclusion criteria were enrolled for the study.04 patients dropped out due to their personal reasons. In this clinical trial the assessment of the results was done on 16 patients, with total 07 patients in Group I and 09 in Group II.

A total of 93.76% patients showed signs of marked improvement symptomatically (Table no.2)

In trial GroupI,85.71% of the patients have shown marked improvement while 14.28% patients didn't show improvement in their symptoms. In trial Group II 100 % patients had shown marked improvement.

37.5% patients showed marked improvement,37.5% patients showed moderate improvement while 25% patients didn't improve

In functional criteria (Table no.4)-

In GroupI,14.28% showed marked improvement, 42.85% showed moderate improvement while 42.85% didn't show improvement. In Group II, 55.55% patients showed marked improvement 33.33% patients showed moderate improvement while 11.11% patients didn't show improvement)

In objective parameters, 56.25% patients showed marked improvement, 18.75% showed moderate improvement and 25% patients didn't show improvement (Table no.8)

In Group I,57.14% have shown marked improvement 14.28% showed moderate improvement while 28.57% didn't show improvement. In Group II, 55.55% have shown marked improvement 22.22% showed moderate improvement while 22.22% didn't show improvement in their FEV_1 %)**.** Scores of both questionnaires were improved in all the patients

CONCLUSION

It can be assumed that there was a moderate improvement in both trial groups and the chosen drugs can be beneficial for the patients of COPD. The formulations in Group II have shown superior effects than those of Group I. On observing the results, it can be summarized that the trial drug has shown mucolytic, expectorant, mild anti-inflammatory and potent bronchodilator actions which helped the patients to achieve symptomatic relief. Hence, it can be concluded that for the prevention of progression of disease *Ayurvedic* herbal formulations can prove to be beneficial.

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