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Clinical Researches

Efficacy of *Vasadi Syrup* and *Shwasaghna Dhuma* in the patients of COPD *(Shwasa Roga)*

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) threatens as emerging public health crisis. The two major drivers for this are the ageing of the world's population and the impressive, if deplorable, success of the multinational tobacco companies at forcing open world markets. One of the most striking aspect of COPD is that it is heterogenous. There are many different presentations with differing intensities of symptoms and even differing responses to the medication. Sorting out, what accounts for this phenomenon and how treatments can be best individualised, is of concern to both basic and clinical scientists. COPD is a leading cause of morbidity and mortality worldwide and results in a substantial economic and social burden to society. It is the sixth most common cause of death worldwide and expected to rise to third position by 2020. Several national and international agencies like WHO, GOLD, ATS, ERS etc. are working in a direction of finding some solution of this wicked problem. In *Ayurvedic* texts *Shwasa Roga* has been described having symptomatology close to COPD. A study was carried out in P.G. Deptt. of Kayachikitsa in R.G.G.P.G. Ayu. College Paprola, H. P. where the role and efficacy of two *Ayurvedic* formulations -*Vasadi Syrup and Shwasaghna Dhuma* was evaluated on 30 patients of COPD selected on the basis of fixed inclusion and exclusion criteria in two different groups. In both the groups drugs provided significant results based on subjective symptomatological criteria and objective spirometric criteria.

Key words: Chronic Obstructive Pulmonary Disease, *Shwasa Roga, Vasadi Syrup, Shwasaghna Dhuma*..

Introduction

'Shwasa Roga' is a disease of *'Pranavaha srotas'* (Tracheobronchial tree). The abnormal, rapid or difficult breathing when present as a cardinal feature of a disease is called *'Shwasa roga'*.When *Prana Vayu* get vitiated and becomes defiled, get obstructed by *Kapha* and moves in opposite direction i.e. upwards and unable to perform normal functions, this condition is termed as *Shwasa roga*[1], which is described elaborately in almost every *Ayurvedic* text. This closely resembles Chronic Obstructive Pulmonary Disease (COPD). GOLD has defined COPD as a preventable and treatable disease with some significant extrapulmonary effects that may contribute to the severity in individual patients. Its pulmonary component is characterised by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and associated with an abnormal inflammatory response of the lung to noxious particles or gases"[2]. It is currently the fourth leading cause of death worldwide and by 2020 it is expected to rise to third position[3]. But as far as awareness among the people is concerned, COPD remained under recognised, underdiagnosed, and under treated disease.

Now, the time has come that the physicians should come forward with some definite solutions to this problem.In the same series study has been carried out to evaluate the efficacy of two *Ayurvedic* formulations i.e.*Vasadi syrup* and *Shwasaghna dhuma* in these patients so that the progression of disease can be controlled and patients should be provided relief in symptomatology and hence better life.

Aims and objectives

(i) To evaluate the efficacy of trial drug in the management of COPD.

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(ii) To study the reversibility of disease process if any with the help of spirometric parameters.
(iii) To study the beneficial and adverse effect of the trial drug.

Material and Methods

To conduct this study patients diagnosed with COPD fulfilling the inclusion criteria were registered from OPD/IPD of R.G.G.P.G.A.C. and associated hospital, Paprola Distt.-Kangra (H.P.), irrespective of sex, caste, religion. Patients between the age group of 30 to 70 years were selected.

Inclusion Criteria

Selection of the patients was done on the basis of three criteriae viz. Symptomatological criteria, Radiological and Spirometric criteria (given by GOLD 2006)[2].

Exclusion Criteria

Any patient not fulfilling the inclusion criteria, not willing for trial, below 30 years or above 70 years of age and presented with complications were excluded from the study.

Selection of Trial Drugs & Preparation

In the present study those drugs were selected which predominantly have *Vata* and *Kapha* pacifying properties, which are the main *doshas* vitiated in the disease concerned. They have bronchodilatory, mucolytic, expectorant and antimicrobial actions. *Vasadi kwatha* in syrup form has been taken from *Yogaratnakara*[4] and *Shwasaghna dhuma* has been taken from *'Anubhutayoga prakaran'* of *Bhaishajya Ratnavali*[5].

Vasadi kwatha in syrup form was prepared from Ayush Herbs Pharmaceuticals at Nagrota Bagwan, Dist. Kangra (H.P.). Drugs for the same were procured from some private herbs dealer in the local market. One kg of each herb was taken in which eight times water was added and boiled till one-fourth was left. Now 24 kg sugar was added to it total 40 lt. syrup was prepared.

Shwasaghna dhuma was prepared at college pharmacy of R.G.G.P.G. Ayu. College, Paprola. Drugs were procured from local herb dealer.*Yavkuta* of drugs was prepared.

Administration

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: Twenty patients were given *Vasadi Kwatha* in syrup form in a dose of 15ml thrice a day after meals for 30 days.

Contents of *Vasadi syrup: Vasa, Haridra, Dhanyaka, Bharangi, Guduchi, Shunthi, Kantakari, Pippali*. Each herb is taken in equal amount as *kwatha dravya* and *Maricha churna* as *prakshepa dravya*.

Trial Group-II: Ten patients were given *Shwasaghna dhuma* in a dose of 2 puffs/1g , twice a day after meals for 30 days using a smoke-pipe.Duration of inhalation of the drug varied according to the patient's own vital capacity.

Contents of *Shwasaghna dhuma*: *Yavakuta churna* of seeds of *Kantakari*, Dry leaves of *Dhatura, Ajowan, Khurasani ajowan, Kalmishora, Haridra and Bhanga* in equal parts.

Gradation of Subjective and Functional Symptoms (Subjective parameters)

Symptoms / Grades	1	2	3	4	5
1. Breathlessness	Absent.	On unaccustomed work.	On accustomed work.	Even at rest.	
2. Cough	No cough.	Twice in 24 hrs. without exhaustion.	3 to 4 times in 24 hrs. without exhaustion.	Most of the time in 24 hrs. with exhaustion.	
3. Expectoration	5 to 10 ml. thin.	10 to 20 ml. thin.	25 to 50 ml. thick.	50 to 100 ml thick, tenacious.	
4. Heaviness in the Chest	No Heaviness.	Mild relieved by expectoration.	Moderate not relieved by expectoration.	Severe and remain through out the day.	
5. Wheezes	Not present.	Twice in 24 hrs.	Three to four time in 24 hrs.	Throughout the day.	
6. Cyanosis	No cyanosis.	Mild peripheral.	Mild mixed.	Moderate mixed.	Gross Mixed.
7. Edema	Not present.	Present on pedal and pretibial region.	Present over whole lower limb.	Present all over body.	
8. Sleep duration with posture	Sleep in any posture (6-8 hrs.).	Sleep in propped up position (4-6 hrs.).	Sleep in sitting posture (1-2 hrs.).	Cannot sleep in any posture.	
9. Power of exertion 100 mts. walk	Less than 50 seconds.	Between 50-69 seconds.	Between 70-89 seconds.	More than 90-seconds.	
10. Breath holding time	50-60 seconds.	40-50 seconds.	30-40 seconds.	Less than 30 seconds.	
11. Intervention with allopathic drugs	No need.	Need occasionally.	Need once daily.	Need thrice daily.	
12. Pulse Rate	Between 70-89 per minute.	Between 90-99 per minute.	Between 100-109 per minute.	Over 110 per minute.	

Staging of Obstruction on the Basis of Spirometry (Objective parameter)[2]

Grade	Obstruction	Severity
1	Mild obstruction	$FEV_1 \geq 80\%$ of predicted.
2	Moderate obstruction	$50\% \leq FEV_1 < 80\%$ of predicted.
3	Severe obstruction	$30\% \leq FEV_1 < 50\%$ of predicted.
4	Very severe obstruction	$FEV_1 < 30\%$ of predicted or $FEV_1 < 50\%$ + Ch. respiratory failure

Assessment of overall effect

Categories	Subjective criteria	Objective criteria
Markedly Improved	>40% improvement over its pre trial value	> 10% improvement in FEV_1 over its pre trial value.
Improved	20% to 39% improvement	1 to 10% improvement in FEV_1 over its pre trial value.
Not Improved	< 20% improvement	< 1% or no change in FEV_1over its pre trial value.
Deteriorated	Deterioration in all subjective symptoms	Deterioration in FEV_1 over its pre trial value.

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 spirometric $FEV_{1(L)}$

Criteria for assessment

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

Observations

In this clinical study total 30 patients were registered. Six patients i.e.4 in group I and 2 in group II out of 30 could not complete the trial, hence considered as dropout cases. General observations includes data gathered from all the 30 patients whereas only 24 patients i.e.16 in group I and 8 in group II were evaluated statistically.

In the present study maximum number of the patients i.e. 25 (83.3%) were males and belonged to (50-70yrs.) of age group. Most of the patients i.e.29 (96.7%)were having active life style. The 16 patients i.e. 53.3% were illiterate and were ignorant about the various factors which affected their health status. The 22 patients i.e.73.4% were farmers and labourers and 86.7% of the patients were belonging to lower socioeconomic class. The 29 patients i.e.90% were smokers and 81.47% of them were having chronicity of 25-35yrs.Observations on various clinical features showed that the main presenting complaints of the patients were breathlessness, cough, expectoration and fatigue. It was also observed that reduced air entry, added sounds and chest resonance were present in all the patients i.e.100%.

Results

The effects of the therapy on main symptomatological criteria like breathlessness, cough, expectoration, heaviness in chest was statistically highly significant in both the trial groups ($p<0.001$) (Table 1 & 4). Statistically significant improvement was observed in breath holding time and power of exertion in both the trial groups (Table 2 & 5). Statistically significant improvement was observed in spirometric parameters like $FEV_{1(L)}$ ($p<0.05$) and $FEV_1/FVC\%$ ($p<0.01$) in trial group I, whereas it was statistically insignificant in trial group II ($p>0.05$) (Table 3 & 6).

No significant effect on the Hb gm% was observed in both the trial groups. Statistically significant reduction in the ESR was observed with ($p< 0.01$) in trial group I and ($p<0.05$) in trial group II.

The overall effects of the therapies were encouraging as all patients have shown improvement symptomatologically. In trial group I, 10 patients i.e. 62.5% were markedly improved, while 6 patients 37.5% were improved. In trial group II, 4 patients i.e.50% have shown marked improvement whereas other 4 patients i.e.50% have shown improvement only. On objective (spirometric) parameters marked improvement was observed in 6 i.e.40% patients, while improvement was recorded in 8 i.e. 53.34% and 1 patient i.e. 6.66% has deteriorated . In trial groupII,3 patients i.e.50% have shown marked improvement, followed by improvement in 2 patients i.e. 33.3% while 1 patient i.e. 16.7% have not shown any improvement (Table 7 & 8).

Table 1: Effect of trial drug on main clinical features of COPD w.r.to grades in trial Group I:

Sr. No.	Features	Mean score		%relief	SD±	SE ±	t	p
		BT	AT					
1.	Breathlessness	3.0	1.625	45.83	0.500	0.125	11	<0.001
2.	Cough	3.75	1.687	54.98	0.25	0.0625	33	<0.001
3.	Expectoration	2.875	1.437	50.01	0.632	0.158	9.493	<0.001
4.	Heaviness in chest	2.812	1.312	53.35	0.966	0.241	6.211	<0.001
5.	Wheezes	1.437	1.000	30.43	0.892	0.223	1.961	>0.05
6.	Cyanosis	2	1.062	46.85	1.181	0.295	3.174	<0.01
7.	Edema	1.25	1	20	0.447	0.111	2.236	<0.05

Table 2: Effect of trial drug on main functional criteria of COPD w.r.to grades in trial Group I

Sr. No.	Features	Mean score		%relief	SD±	SE ±	t	p
		BT	AT					
1.	Pulse rate	1.812	1.50	17.21	0.680	0.170	1.838	>0.05
2.	Breath holding time	2.562	1.75	31.69	0.655	0.163	4.963	<0.001
3.	Power of exertion	3.187	1.687	47.06	0.516	0.129	11.627	<0.001
4.	Sleep pattern	1.437	1.00	30.41	0.512	0.128	3.417	<0.01
5.	Intervention with Allopathic drugs	2.187	1.312	40.00	0.806	0.201	4.342	<0.001

Table 3: Effect of trial drug on objective (spirometric) parameters in Trial Group-I

Sr. No.	Parameters	Mean score		% relief	SD±	SE ±	t	p
		BT	AT					
1.	$FVC_{(L)}$	1.821	1.906	4.667	0.4484	0.1121	0.033	>0.05
2.	$FEV_{1(L)}$	0.942	1.103	17.039	0.247	0.0617	2.60	<0.05
3.	FEV_1 / FVC%	51.00	57.13	12.01	6.603	1.650	3.715	<0.01

Table 4: Effect of trial drug on main clinical features of COPD in terms of grades in trial Group II

Sr. No.	Features	Mean score		% relief	SD±	SE ±	t	p
		BT	AT					
1.	Breathlessness	2.625	1.625	38.09	0.5345	0.1890	5.291	<0.01
2.	Cough	3.5	2	42.85	0.5345	0.1890	7.936	<0.001
3.	Expectoration	2.75	1.375	50.00	0.5174	0.1829	7.517	<0.001
4.	Heaviness in chest	2.25	1.125	50.00	0.8342	0.2949	3.814	<0.01
5.	Wheezes	1.625	1.00	38.46	0.9160	0.3239	1.929	>0.05
6.	Cyanosis	2.25	1.375	38.88	0.9910	0.3504	2.497	<0.05
7.	Edema	1.0	1.0	0.00	0.00	0.00	0.00	>0.05

Table 5: Effect of trial drug on main functional criteria of COPD in terms of grades in trial group II

Sr. No.	Features	Mean score		% relief	SD±	SE ±	t	p
		BT	AT					
1.	Pulse rate	2.50	2.0	20.00	0.534	0.189	2.645	<0.05
2.	Breath holding time	2.75	1.62	40.90	0.834	0.294	3.814	<0.01
3.	Power of exertion	2.87	1.5	47.82	0.744	0.263	5.228	<0.01
4.	Sleep pattern	1.25	1.0	20.00	0.462	0.163	1.528	>0.05
5.	Intervention with Allopathic drugs	2.25	1.25	44.44	0.534	0.189	5.291	<0.01

Table 6: Effect of trial drug on objective (spirometric) parameter in trial Group-II

Sr. No	Features	Mean Score		%relief	SD±	SE ±	t	p
		BT	AT					
1.	$FVC_{(L)}$	2.145	2.228	3.869	0.2826	0.0999	0.838	>0.05
2.	$FEV_{1(L)}$	1.50	1.60	6.66	0.2019	0.0714	1.99	>0.05
3.	FEV_1 / FVC%	67.91	70.35	3.590	9.623	3.403	0.716	>0.05

Table 7: Overall effect of therapies on subjective symptoms in trial Group -I and II

Sr. No	Results	Trial Group-I		Trial Group-II	
		No. of Patients	Percentage	No. of Patients	Percentage
1.	Markedly Improved	10	62.5	4	50
2.	Improved	6	37.5	4	50
3.	Not Improved	0	0	0	0
4.	Deteriorated	0	0	0	0

Table 8: Overall effect of therapies on objective (Spirometric) criteria in trial Group -I and II

Sr. No.	Results	Trial Group-I		Trial Group-II	
		No. of Patients	Percentage	No. of Patients	Percentage
1.	Markedly Improved	6	40	3	50
2.	Improved	8	53.34	2	33.3
3.	Not Improved	0	0	1	16.7
4.	Deteriorated	1	6.66	0	0

Discussion

In this clinical trial the assessment of the results were done on 24 patients, with total 16 patients in group I and 8 in group II. In trial group I where patients were given *Vasadi syrup*,100% of the patients have shown improvement in their subjective and functional symptoms and 93.3% have shown improvement in their FEV_1%. Whereas in trial group II, where patients were given *Shwasaghna dhuma*, it was observed that 100% of the patients have shown improvement in their subjective and functional symptoms and 50% patients have shown marked improvement in their FEV_1% of predicted, 33.3% have shown improvement only and 16.7% of the patients have neither shown any improvement nor deteriorated.

This improvement was probably because of *ushna*, *tikshna*, *chhedana*, *kaphavatAahara* properties of the drugs which expels out *lina Kapha dosha*, cleanses the *srotas* & in modern point of view having antiinflammatory, bronchodilatory, mucolytic, expectorant actions, which interrupt the pathogenesis of the disease.

Conclusion

On the basis of this study, it can be concluded that the trial drugs *Vasadi syrup* as well as *Shwasaghna dhuma* both have a beneficial role in the management of COPD. No untoward effects of the drugs were noted during the trial and follow up period. In a disease like COPD, for the prevention of the progression of the disease to a crippling stage we have to manage this disease effectively and expeditiously. In this progressive disease *Ayurvedic* formulations can be proved milestone in this regard.

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हिन्दी सारांश

श्वास रोग में आयुर्वेदिक औषधियाँ वासादि सिरप एवं श्वासघ्न धूम के प्रभाव का अध्ययन

प्रवीणकुमार शर्मा, शरद जोहरी एवं बी. एल. मेहरा

श्वास रोग का उल्लेख प्रायः आयुर्वेद के प्रत्येक आर्षग्रन्थ में उपलब्ध है। पुनः पुनः कष्टपूर्वक श्वास लेना ही श्वास रोग है। प्रस्तुत संकलन में आयुर्वेदोक्त श्वास सम्बन्धित मत का आधुनिक सी.ओ.पी.डी. नामक रोग से साम्यता प्रदर्शित करते हुए अमुक रोग में आयुर्वेदीय औषध योगों से होने वाले लाभ को देखा एवं उसका आंकलन किया गया। आधुनिक निदान के आधार पर अंतरंग एवं बहिरंग विभाग से श्वास के ३० रोगियों का चयन किया गया जिन्हें दो श्रेणियों में विभाजित किया गया। प्रथम श्रेणी को वासादि सिरप तथा द्वितीय श्रेणी को श्वासघ्न धूम दिया गया। परिणामों के आंकलन से यह सिद्ध होता है कि दोनों ही आयुर्वेदीय औषधियाँ श्वास रोगों की चिकित्सा में अत्यन्त लाभकारी हैं ।