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Evaluation of efficacy of *Haritakyadi Gutika* and *Vasadi Kwatha* in the Management of *Shwasa Roga* w.s.r. to Chronic Obstructive Pulmonary Disease (COPD)

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ABSTRACT

Shwasa Roga is one of the common and deadliest diseases according to *Ayurvedic* literature and similarly according to modern medical science, Chronic Obstructive Pulmonary Disease (COPD**)** is a common respiratory disease having high morbidity and mortality, whose symptomatology resembles to *Shwasa Roga*. It affects all socioeconomic groups equally all over the world and its prevalence is increasing day by day. Morbidity and mortality of the disease is also rising with the passing years. It not only affects respiratory system but other systemic components also get involved with its progression. There is no absolute cure for this disease but to reduce its morbidity, mortality and fatal complications patient requires long term therapy. So, a controlled clinical study was planned to develop a safe and cost-effective therapy to manage this chronic disease. ***Haritakyadi Gutika*(*Chakradatta Kasachikitsa* 11/30)and *Vasadi Kwatha* (*Yogratnakara Shwasa Nidana* 5)**werethe interventional drugs used in this study whose ingredients were mainly *Tridoshashamaka* and work on *Pranavaha Srotasa.* Study was done on thirty subjects diagnosed with COPD, aged between 45-75 years. Studysubjects were screened from OPD and IPD of Kayachikitsa department of Rajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital Paprola and were diagnosed on the basis of spirometric results. Spirometry was the main tool for inclusion of subjects in this study. Registered subjects were treated for thirty days with above mentioned drugs in group I and tablet Doxofylline in group II. Statistically significant improvement was observed after the completion of therapy in some of the symptoms. *Haritakyadi Gutika* in the dose of 2 gram per day and *Vasadi Kwatha* in the dose of 100 ml per day found to be more effective in cough and expectoration as compared to tablet Doxofylline in the dose of 400 mg per day. On overall assessment therapeutic effect of *Haritakyadi Gutika* and *Vasadi Kwatha* was found to be comparable to the standard drug i.e., tablet Doxofylline. As per the safety concern no untoward effect of drugs seen during the entire trial period.

Key Words *Shwasa Roga,* COPD, *HaritakyadiGutika, Vasadi Kwatha, Spirometry*

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INTRODUCTION - *Shwasa Roga* is one of the commonest and fatal diseases according to both *Ayurveda*[1] and Modern medical sciences if not managed timely and properly. The disease is

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prevalent in 4th decade of life[2] with male predominance[3]. Generally, the word *Shwasa* is used to describe both normal respiration in physiological condition as well as difficult breathing or *Shwasakrichrata* in pathological condition[4]. *ShwasaRoga* is a common disease of *Pranavaha Srotasa*[5] or trachea-bronchial tree whose cardinal feature is abnormal, rapid[6] or difficult breathing. *Kapha* increases broncho-pulmonary secretions which get thickened by the antagonizing properties of *Vata* and leads to *Srotosanga*. The parallel disease in modern medicine is Chronic Obstructive Pulmonary Disease which has similar cardinal feature and characterized by airflow limitation that is usually progressive[7]. Other than the pulmonary involvement primarily disease is also having systemic component which is characterized by impaired nutrition, weight loss, skeletal muscle dysfunction, anaemia/polycythaemia etc.[8]. Cumulative exposure of tobacco smoke, occupational dust vapors, indoor and outdoor pollution is responsible for the disease[9]. The males of 45 – 80 years age group are mainly affected. It is one of the most distressing disease common in all socioeconomic groups and is 3rd leading cause of death currently[10,11].Management of this disease is difficult due to number of associated clinical manifestations and its fatal complications. It also imposes financial burden on individual as the long-term therapy is required. So, in order to reduce morbidity, mortality present study was planned to develop a safe and cost-effective therapy to manage this chronic disease. ***Haritakyadi Gutika* and *Vasadi Kwatha*** were selected for the present clinical study. Primary objective of this research work was to evaluate the efficacy and assess the safety of *Haritakyadi Gutika* and *Vasadi Kwatha* in the management of *Shwasa Roga* w.s.r. to COPD.Intervention with these drugs for 30 days showed statistically significant improvement in symptoms without any adverse effect.

MATERIALS AND METHODS

A controlled clinical study with two study groups was designed. Subjects were screened from OPD/IPD Dept. of Kayachikitsa R.G.G.P.G. Ayu. College & Hospital Paprola, irrespective of gender, cast and religion; among them 30 were registered for the research work who were diagnosed with COPD and fulfilling the inclusion criteria. Diagnosis was made on the basis of signs, symptoms, radiological findings in chest and spirometric result i.e. post bronchodialation FEV1/FVC < 70% or < 0.7[12,13]. Spirometry was performed after fifteen minutes of bronchodialation with 2 puff of Salbutamol, 100mcg/puff.

All the registered patients were randomly divided into two groups, each group had fifteen patients.In group I patients *Haritakyadi Gutika* (1g twice a day) and *Vasadi Kwatha* (50 ml twice a day) were used for the management whereas in group II tablet Doxofylline (400 mg once a day) was used. Ingredients of *Haritakyadi Gutika* are – *Haritaki, Shunthi, Mustaka, Guda* and that of

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Vasadi Kwatha are – *Vasa, Haridra, Dhanyaka, Bharangi, Guduchi, Shunthi, Kantkari, Pippali and Maricha.* Part used and quantity of each raw drug has been mentioned in table no. 1 and 2, respectively. Both the formulations were prepared as per standards of GMP in the Charaka PharmacyRajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital Paprola, Distt. Kangra (H.P.). Therapy was given for thirty days and patients were advised to come for follow up after fifteen days of initiation of therapy and at the end of trial.

Table 1 Ingredients of *Haritakyadi Gutika*

Sr. No.	Ingredients	Botanical Name	Family	Part used	Quantity
1.	*Haritaki*	*Terminalia chebula* Retz.	Combretaceae	Pericarp	1 part
2.	*Shunthi*	*Zingiber officinalis* Rose.	Zingiberaceae	Rhizome	1 part
3.	*Mustaka*	*Cyperus rotundus* Linn.	Cyperaceae	Rhizome	1 part
4.	*Guda*				1 part

Table 2 Ingredients of *Vasadi Kwatha*

Sr. No.	Ingredients	Botanical Name	Family	Part used	Quantity
1.	*Vasa*	*Adhatoda vasica* Nees.	Acanthaceae	Leaves	1 part
2.	*Haridra*	*Curcuma longa* Linn.	Berberidaceae	Rhizome	1 part
3.	*Dhanyaka*	*Coriandrum sativum* Linn.	Umbelliferae	Seed	1 part
4.	*Bharangi*	*Clerodendron serratum* Linn.	Verbenaceae	Root	1 part
5.	*Guduchi*	*Tinospora cordifolia* Willd. Miers	Rutaceae	Stem	1 part
6.	*Shunthi*	*Zingiber officinalis* Rose.	Zingiberaceae	Rhizome	1 part
7.	*Kantkari*	*Solanum indicum* Linn.	Solanaceae	Whole part	1 part
8.	*Pippali*	*Piper longum* Linn.	Piperaceae	Fruit	1 part
9.	*Maricha*	*Piper nigrum* Linn.	Piperaceae	Fruit	3g/100g

Investigations done before and after completion of therapy are- Chest X-ray PA view, spirometry, pulse oximetry; Hematological investigations - Hb%, TLC, DLC, ESR**;** Biochemical investigations – FBS; TSB, DSB, SGOT, SGPT; B.Urea, S. Creatinine.

Patients suffering from malignancy, pulmonary tuberculosis, renal failure, diabetes mellitus, congestive heart failure, ischemic heart disease, severe anemia, myocardial infarction, poorly controlled hypertension, having advanced type II respiratory failure, lung collapse and pneumothorax were excluded. Subjects having more than 12% increment in FEV_1/FVC in fifteen minutes of bronchodialation with 200 mcg Salbutamol were also excluded.

All the patients were evaluated on the basis of subjective and objective criteria. Subjective parameters for the assessment were **– dyspnoea, cough, expectoration, heaviness in chest, wheezing, cyanosis, and requirement of inhaler** as given in table no. 3**.**Objective parameters were – **FEV_1/FVC%, SPO_2 at room air and pulse rate.**

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Table 3 Subjective Criteria

Sr. no.	Sign and Symptoms	Degree of severity	Grade
1.	Dyspnoea	No dyspnoea	0
		Dyspnoea on prolong and heavy exertion	1
		Dyspnoea on moderate exertion	2
		Dyspnoea on mild exertion	3
		Dyspnoea even at rest	4
2.	Cough	No cough	0
		Twice in a day; without much exhaustion	1
		Three to four times in a day; without much exhaustion	2
		Most of the time in a day; with exhaustion	3
		Throughout the day; with marked exhaustion	4
3.	Expectoration	Less than 5 ml	0
		5 to 10 ml; thin	1
		10 to 20 ml; thin	2
		25 to 30 ml; thin	3
		50 to 100 ml; tenacious	4
4.	Heaviness in chest	No heaviness	0
		Mild; with occasional wheezing	1
		Mild; relieved by expectoration	2
		Moderate; relieved by expectoration	3
		Severe; with wheezing throughout the day	4
5.	Wheezes	Not present	0
		Twice in 24 hours	1
		Three to four times in 24 hours	2
		Five to six times in 24 hours	3
		Throughout the day	4
6.	Cyanosis	Not present	0
		Mild peripheral	1
		Mild peripheral and central	2
		Moderate peripheral and central	3
		Gross peripheral and central	4
7.	Requirement of inhaler	Not required	0
		Required occasionally	1
		Required once daily	2
		Required twice daily	3
		Required more than twice a day	4

RESULTS AND DISCUSSION

In the present study out of thirty registered patients eighteen were male and twelve were female, twenty one patients were in the age group of 65-75 years.Twenty two patients were of low socioeconomic status. Eighteen patients were leading sedentary life. Sixteen patients were active smoker and ten were ex-smoker. Many previous studies have also revealed that the disease is male predominant, uncommon in younger age with high prevalence in smokers and low socioeconomic groups and makes the patients unable to lead an active life with passage of time. Other than difficult breathing cough and sputum production are commonly associated which are usually first symptoms[14]. The airflow limitation is not fully reversible[15] which occur due to irreversible damage of the airways and increases with age and continuous exposure to aetiological factors. That's why with time severity of disease increases.

The interventional drugs used in this study i.e., *Haritakyadi Gutika* and *Vasadi Kwatha* showed statistically highly significant improvement in

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cough and expectoration whereas statistically significant reduction in dyspnoea, wheezing, heaviness in chest and requirement of inhaler therapy; as shown in table no. 4. They also showed statistically significant improvement in oxygen saturation; given in table no. 5.

Table 4 Effect of therapy on subjective parameters

Subjective Parameters	Group	Mean Score		% Change	Mean Diff.	S.D.±	S.E.±	t-value	p-value
		BT	AT						
Dyspnoea	Gr-I	1.533	1.067	30.40	0.466	0.516	0.133	3.500	0.004*
	Gr-II	1.733	0.733	57.70	1	0.378	0.098	10.247	<0.001**
Cough	Gr-I	1.533	0.600	60.86	0.933	0.258	0.067	14	<0.001**
	Gr-II	1.533	1.333	13.05	0.200	0.676	0.145	1.146	0.271
Expectoration	Gr-I	1.600	0.800	50.00	0.800	0.676	0.175	4.583	<0.001**
	Gr-II	1.600	1.133	29.19	0.467	0.516	0.133	3.500	0.004*
Heaviness in chest	Gr-I	0.533	0.267	49.90	0.266	0.458	0.118	2.256	0.041*
	Gr-II	1	0.467	53.30	0.533	0.516	0.133	4	0.001*
Wheezing	Gr-I	1.067	0.667	37.48	0.400	0.632	0.163	2.449	0.028
	Gr-II	1.267	0.400	68.43	0.867	0.352	0.091	9.539	<0.001**
Cyanosis	Gr-I	0.333	0.267	19.82	0.066	0.258	0.067	1.00	0.334
	Gr-II	0.333	0.200	39.94	0.133	0.352	0.091	1.468	0.164
Requirement of inhaler	Gr-I	1.6	1.2	25	0.400	0.507	0.131	3.055	0.009*
	Gr-II	1.667	0.867	47.99	0.8	0.561	0.145	5.527	<0.001**

Table 5 Effect of therapy on objective parameters

Objective parameters	Group	Mean Score		% Change	Mean Diff.	S.D.±	S.E.±	t-value	p-value
		BT	AT						
SPO_2 (at room air)	Gr-I	89.800	90.333	0.59	0.533	0.743	0.192	2.779	0.015*
	Gr-II	89.267	90.733	1.64	1.467	0.834	0.215	6.813	<0.001**
FEV_1/FVC	Gr-I	0.641	0.644	0.47	0.003	0.007	0.002	1.468	0.164
	Gr-II	0.649	0.653	0.62	0.004	0.007	0.002	2.103	0.054
Pulse rate	Gr-I	86.733	86.267	0.54	0.467	0.516	0.336	1.388	0.187
	Gr-II	85.200	84.867	0.39	0.333	2.059	0.532	0.627	0.541

On intergroup comparison statistically highly significant difference was observed between both the groups in respect to cough whereas statistically significant difference was found in respect to dyspnoea, wheezing, requirement of inhaler and oxygen saturation; given in table no. 6 and 7. Overall effect of therapy has been shown in table no. 8.

Table 6 Intergroup comparison of effect of therapy on subjective parameters

Subjective parameters	Mean Diff.		%Change		S.D.±		t-value	
	Gr-I	Gr-II	Gr-I	Gr-II	Gr-I	Gr-II		p-value
Dyspnoea	0.467	1	30.40	57.70	0.516	0.378	3.227	0.003*
Cough	0.933	0.200	60.86	13.05	0.258	0.676	3.924	<0.001**
Expectoration	0.800	0.467	50	29.19	0.676	0.516	1.517	0.141
Heaviness in chest	0.267	0.533	49	53.30	0.458	0.516	1.493	0.147
Wheezing	0.400	0.867	37.48	68.43	0.632	0.352	2.500	0.019*
Cyanosis	0.066	0.133	19.82	39.94	0.258	0.352	0.588	0.561
Requirement of inhaler	0.400	0.800	25	47.99	0.507	0.561	2.049	0.050*

Table 7 Intergroup comparison of effect of therapy on objective parameters

Objective parameter	Mean Diff.		%Change		S.D.±		t-Value	p-Value
	Gr-I	Gr-II	Gr-I	Gr-II	Gr-I	Gr-II		
SPO_2 (at room air)	0.005	0.014	0.59	1.64	0.007	0.008	3.28	0.003
FEV_1/FVC	0.003	0.004	0.47	0.62	0.007	0.007	0.494	0.625

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Pulse rate	0.467	0.333	0.54	0.39	1.302	2.059	0.213	0.833

Table 8 Overall assessment of therapy (on the basis of improvement in subjective parameters)

Group	Unimproved (<25%)	Mild Improvement (25-50%)	Moderate Improvement (51%-75%)	Marked Improvement (76-99%)	Total
I	3	5	4	3	15
II	0	12	1	2	15

+

Table 9 Pharmacological properties of drugs

Drug	*Rasa*	*Guna*	*Virya*	*Vipaka*	*Karma*
Haritaki	*Pancharasa Yukta (Lavan Rahita)*	*Laghu, Ruksha*	*Ushna*	*Madhura*	*Tridoshahara, Rasayana, Deepana, Pachana , Vatanulomaka, Shwasa-Kasahara*
Shunthi	*Katu*	*Laghu, Snigdha*	*Ushna*	*Madhura*	*Kapha-Vataghna, Deepana, Shwasa-Kasahara*
Mustaka	*Tikta, Katu, Kashaya*	*Laghu, Ruksha*	*Sheeta*	*Katu*	*Kapha-Pittahara, Deepana, Pachana,*
Vasa	*Tikta, Kashaya*	*Laghu, Ruksha*	*Sheeta*	*Katu*	*Kapha-Pittaghna, Shwasa-Kasahara*
Haridra	*Katu, Tikta*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha-Vatashamaka, Lekhana, Bhedana*
Dhanyaka	*Tikta, Katu, Kashaya, Madhura*	*Laghu, Snigdha*	*Ushna*	*Madhura*	*Tridoshahara, Deepana, Paachana, Vatanulomana, Shwasa-Kasahara*
Bharangi	*Tikta, Katu, Kashaya*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha-Vata Shamaka, Deepana, Pachana, Shwasa-Kasahara, Vatanulomana*
Guduchi	*Tikta, Katu, Kashaya*	*Guru-Snigdha*	*Ushna*	*Madhura*	*Tridoshashamaka, Rasayana, Deepana*
Kantakari	*Tikta, Katu*	*Laghu, Ruksha*	*Ushna*	*Katu*	*Kapha-Vatashamaka, Deepana, Paachana, Shwasa-kasahara, Vatanulomana*
Pippali	*Katu*	*Laghu, Snigdha, Tikshna*	*Ushna*	*Madhura*	*Kapha-Vatashamaka, Deepana, Paachana, Shwasa-Kasahara, Rasayana*
Maricha	*Katu*	*Laghu, Tikshna*	*Ushna*	*Katu*	*Kapha-Vataghna, Chedana, Pramathi, Deepana, Paachana, Shwas-Kasahara*

As there is involvement of vitiated *Vata, Kapha* and pathology in *Pitta Sthana* in the pathogenesis of *Shwasa Roga*[16], the drugs with *Vatakaphaghana, Vatanulomaka* and *Pittashamaka* properties were used in this study so that *Samprapti Vighatan* can be done in order to prevent the development and progression of the disease. In these selected formulations there is a balance of *Tridoshashamaka Rasa, Sheeta-Ushana Virya* and *Madhura-Katu Vipaka;* as shown in table no. 9. Due to these properties the interventional drugs showed good therapeutic effect. For example- *Haritaki* is *Tridoshashamaka and* due to its *Deepana, Paachana* properties it helps in *Agnivardhan, Aampachana*. In addition to this due to *Bhedana* property it removes *Srotosanga* thus *leads* to *Vatanulomana.Guda* helps in translocation of ingested dust particles from the lungs to the tracheobronchial lymph nodes[17].

CONCLUSION

This study showed that *Haritakyadi Gutika* and *Vasadi Kwatha* have promising results in

symptomatic management of *Shwasa Roga* without any untoward effect. Mainly they are beneficial in relieving cough and expectoration. They also showed reduction in inhalers dependence of registered patients. Therapeutic effect of these drugs is comparable to the standard drug used in management of COPD i.e., tablet Doxofylline. As this disease is not fully curable and requires long term therapy along with frequent hospitalization due to acute exacerbations which imposes financial burden on individual and society. In addition to this long term use of steroids, β_2 sympathomimetics which are frequently used in advanced disease causes some ill effects[18]. So, the study was done to establish such a cost effective treatment module which reduces the requirement of such drugs. This thirty days trial showed that *Haritakyadi Gutika* and *Vasadi Kwatha* are safe and good therapeutic agents for COPD.

Due to COVID-19 Pandemic the study was done on a small sample and only for one month. It can be done on a large sample for a longer duration to evaluate the long term effects of these drugs.

Ethics Approval: vide certificate no. Ayu/IEC/2018/1178

CTRI Registration:vide CTRI no. CTRI/2021/01/030640 dated 20/01/2021.

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Conflict of interest: None

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