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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFECT OF *BHARANGYADI KWATHA* AND *KALIPHALA CHURNA* IN THE MANAGEMENT OF *SHWASA ROGA* W.S.R. TO CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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ABSTRACT

Shwasa Roga is a disease of *Pranavaha Srotas*. Ayurvedic literature reveals that *Prana Vayu* in its physiological form is responsible for normal respiration. But when vitiated *Vata* predominately *Prana Vayu* is obstructed by *Kapha* and moves in opposite direction (upward) then it leads to *Shwasa Roga*. COPD is difficult to treat due to pulmonary as well as systemic involvement and its fatal complications. There is a need for disease prevention and disease management initiatives. It affects the individual physically, socially, financially and even emotionally. So there is need to explore and establish an effective treatment module having least or no side effects with evident therapeutic potential. This study was conducted to find out an effective drug therapy for the management of this disease with least or no side effects. The trial was done on 30 registered patients who were diagnosed with *Shwasa Roga* w.s.r to COPD and were randomly divided in two groups, consisting 15 patients in each group. *Bharangyadi Kwatha* and *Kaliphala (Vibhitak) Churna* were the trial drugs, whereas Doxofylline was the standard drug. 15 patients of group I were given *Bharangyadi Kwatha* in the dose of 25ml twice a day and *Kaliphala Churna* in the dose of 5gm twice a day with *Madhu*. 15 patients of control group were given Tab. Doxofylline 400mg once a day. Assessment of various subjective and objective parameters was done before and after the trial. Obtained data was tabulated and statistically analysed.

INTRODUCTION

Respiratory disorders are common cause of morbidity and mortality all over the world. Both Ayurveda and Modern medical science have described them in their own way. In *Charaka Samhita* specific *Samprapti* (pathogenesis) w.r.t. *Shwasa Roga* has been described as: When *Vayu* preceded by *Kapha* obstructs the passages and itself being obstructed, produces *Shwasa* (dyspnoea)[1]. Symptomatology and etiopathogenesis of *Shwasa Roga* described in Ayurvedic literature closely resemble that of Chronic Obstructed Pulmonary Disease (COPD).

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There are many fatal diseases but they do not take away the life so quickly as *Hikka* and *Shwasa*. Moreover, in the person suffering from other various disorders, severe *Shwasa* and *Hikka* menifest at the end[2]. These two are predominant in *Kapha* and *Vāta*, arise from the seat of *Pitta* and results in *Shoshna* of heart and the *Dhātus* such as *Rasa* etc. Hence both being similar are regarded as very difficult to overcome and if managed badly they get aggravated further and kill the patient like serpents[3].

Aharaja Nidana includes *Ruksha Ahara Sevana, Vishmashana* (irregular food habits), *Sheetal Jal Pana* (cold water intake), *Adhyasana* (taking meal on meal) and *Viharaja Nidana* includes *Dhooma* (cumulative exposure to smoke), *Vatabhayama* (indoor and outdoor pollution), *Raja* (allergens), *Sheetasthana* (living in cold environment), *Ativyayama* (excessive exercise), *Gramya Dharma* (excessive intercourse), *Ambusevanath* (bathing in cold water continuously for a long period) and other causative factors like

Amapradosha, Anaha, Roukshya, Atitarpan, Dorbalya, Marmanoghata, combined use of Ushna and Sheeta, Atisara, Jwara, Chardi, Pratishyaya, Kshata, Kshaya, Raktapitta, Udawarta, Vishuchika, Alaska, Pandu and Visha Sevana results in *Shwasa Roga*[4] and there will be resistance of airways for movement of *Vata (Prana Vayu).* Further increased bronchopulmonary secretions block airways. As a result, person feels difficulty in breathing. *Shwasa Roga* is a disease of *Pranvaha Srotas* or tracheo-bronchial tree whose cardinal feature is abnormal, rapid, or difficult breathing and it resembles that of COPD.

According to Modern texts, for many years, chronic obstructive pulmonary disease (COPD) was defined as "a disease state characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema; the airflow obstruction is generally progressive, may be accompanied by airway hyper-reactivity, and may be viewed as partially reversible." In the past few years, a new definition has been presented by the Global initiative on obstructive Lung disease (GOLD) and by a Task force of the American thoracic society (ATS) and the European respiratory society (ERS). Both GOLD and ATS/ERS state that "COPD is a diseases state characterized by airflow limitation that is not fully revertible. The airflow obstruction is usually both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles and gas." The ATS/ERS definition also states that COPD is both preventable and treatable and that COPD is a systemic disease. A secondary feature of both the GOLD and the ATS/ERS definitions is a scoring system for staging the severity of COPD based upon the post-bronchodilator forced expiratory volume in the first second (FEV1)[5].

People suffered with COPD are at higher risk of health problems. Tobacco smoking is the most common cause of COPD. Other risk factors which contribute for the causation of COPD include, indoor and outdoor air pollution including dust and exposure to occupational irritants such as dust from grains cadmium dust or fumes. Hereditary factors such as deficiency of alpha-1 antiprotease (alpha-1 anti-tripsin deficiency) have also been implicated for causation of disease [6]. In developing countries, the use of coal and biomass such as wood and dry dung as fuel for cooking and heating purposes are common sources of indoor air pollution.

Irrespective of new inventions and advancement in the science, graveness and chronicity of disease is still indicating it as a major health problem. The disease has been marked as *Mahavyadhi* in Ayurvedic treatises. All attempts are made to combat disease and to put forward a good, effective economical drug from the past years.

AIMS AND OBJECTIVES

Primary Objective

1. To evaluate the effect of *Bharangyadi Kwatha* and *Kaliphala Churna* in the management of *Shwasa Roga* w.s.r. to Chronic Obstructive Pulmonary Disease (COPD).
2. To compare the effect of *Bharangyadi Kwatha* and *Kaliphala Churna* with Doxofylline in the management of *Shwasa Roga* w.s.r. to Chronic Obstructive Pulmonary Disease (COPD).

Secondary Objective

To assess the clinical safety of *Bharangyadi Kwatha* and *Kaliphala Churna* in the management of *Shwasa Roga* w.s.r. to Chronic Obstructive Pulmonary Disease (COPD).

Plan of Study

To fulfil the above-mentioned objectives, the research work has been planned in following way:

a. Conceptual study: The available Ayurvedic literature regarding *Shwasa Roga,* modern literature regarding COPD and trial drugs available in different Ayurvedic texts, modern texts, reputed journals, internet and previous studies done in various institutions have been critically reviewed.

b. Clinical study: The study has been carried out to evaluate the effect of *Bharangyadi Kwatha* and *Kaliphala Churna* in comparison to Doxofylline on clinical profile of patients suffering from *Shwasa Roga* (COPD).

MATERIAL AND METHODS

Selection of the Patients

a) The patients were selected from the OPD/IPD Department of *Kayachikitsa* of R.G.G.P.G. Ayurvedic College and Hospital Paprola, Dist. Kangra (H.P.).

b) The minimum sample of 30 patients fulfilling the diagnostic criteria were selected for the trial, which were randomized in two Groups.

Diagnosis of patients

The patients were selected on the basis of subjective and objective criteria

Subjective criteria

Symptoms

- Breathlessness
- Cough
- Expectoration
- Wheezing
- Tightness in the chest

Signs

- Prolonged expiration with pursed lip breathing.
- Barrel shaped chest.
- Central or peripheral cyanosis.
- Use of accessory muscles of respiration.
- Diminished expansion of the chest.
- Reduced air entry.
- Presence of adventitious sounds.

Objective criteria

Radiographic criteria

- Hyper translucent lung field.
- Increased intercostal spaces.
- Low flat diaphragm.
- Narrow or tubular heart.
- Marked or prominent broncho-vascular markings.

Spirometry

Post bronchodilation FEV1/FVC < 70% [15 minutes after bronchodilation with 2 puffs of salbutamol 100mcg/puff.

Pulse Oximetry

Inclusion Criteria

1. Patients willing for trial.
2. Patients who fulfil the diagnostic criteria.
3. Patients of age group 40-80 years of either gender.

Exclusion Criteria

1. Patients not willing to participate in the trial.
2. Patients presenting complications like advanced Type II respiratory failure, lung collapse, pneumothorax etc.
3. Patients suffering from other associated major illness like malignancy, pulmonary tuberculosis, renal failure, diabetes mellitus, congestive heart failure, ischemic heart disease, severe anaemia, myocardial infarction, poorly controlled hypertension etc.
4. Patients below 40 and above 80 years of age.
5. More than 12% increment in FEV1/FVC ratio after bronchodilation with 2 puffs of salbutamol 100mcg/puff.

Investigations

1. Specific - Chest X-ray PA view, Spirometry, Pulse oximetry.
2. Routine examination

Haematological: Hb g%, TLC, DLC, ESR.

Biochemical: FBS, B. Urea, S. Creatinine, TSB, DSB, SGOT, SGPT.

Protocol of Study

- **Screening**- 30 patients of COPD who met the inclusion criteria were enrolled for the study.
- **Consent** - Written and informed consent of patient was taken before inclusion in the trial.
- **I.E.C Approval** - Clinical trial was started after the approval from Institution Ethical Committee of R.G.G.P.G. Ayurvedic College & Hospital, Paprola vide certificate no Ayu/IEC/2022/1341.
- **CTRI Registration-** The trial has been registered in clinical trial registry of India vide CTRI No. CTRI/2023/11/059565 dated 06/11/2023.
- **Patient information sheet**- An information sheet was prepared for the patients registered in the study giving all the details of the study protocols, benefits of the trial and any expected side effects. It was given to all the study subjects registered for the trial.
- **Case Record Form** - A detailed proforma was prepared to note down all the details of the patients and disease including demographic profile, detailed history followed by general physical and systemic examination. Lab investigations were done before commencement of the trial and after completion of therapy, compiled in the case record form.

Selection of trial drugs

The trial drugs *Bharangyadi Kwatha* and *Kaliphala Churna* for the treatment of *Shwasa Roga* (COPD) have been taken from Ayurvedic classics i.e., *Yogaratnakara* and *Chakradutta* respectively.

Interventional drugs

- *Bharangyadi Kwatha (Yogaratnakara)*
- *Kaliphala Churna* (*Chakradutta)*
- *Bharangyadi Kwatha*

अयि प्राणप्रिये जातिफललोहितलोचने ।
भार्गीनागरयोः क्वाथं श्वासत्राणाय पाययेत् ।।[7] (Y.R.Shw.Chi./6)

Table 1: Ingredients of *Bharangyadi Kwatha*

S.No.	Ingredients	Botanical Name	Family	Part used	Form used	Quantity
1	*Bharangi*	*Clerodendrum serratum* (Linn.)	Verbenaceae	Root	Coarse powder (*Yavkut*)	1 part
2	*Shunthi*	*Zingiber officinalis* (Roxb.)	Zingiberaceae	Rhizome	Coarse powder *(Yavkut)*	1 part

Kaliphala Churna

कर्षे कलिफलचूर्ण लीढंचाव्यत्तमधुमिश्रम।

अचिराद्वरति श्वासं प्रबलामुदध्वंरीकांचैव ।[8] (Chak. Hik.shw.chi.pra.12/18)

Table 2: Ingredients of *Kaliphala Churna*

Sr.No.	Ingredients	Botanical Name	Family	Part used	Form used
1	*Kaliphala (Vibhitaki)*	*Terminalia bellirica* (Roxb.)	Combretaceae	Pericarp	Fine powder

Drugs preparation

(1). *Bharangyadi Kwatha*

The drug was prepared according to the standards of GMP in the *Charak* Pharmacy Rajiv Gandhi Govt. Post Graduate *Ayurvedic* College and Hospital Paprola, Dist. Kangra (H.P.) with batch no. R-51/23 and date of manufacturing was 08/11/2023. Chemical analysis of trial formulation was done at drug testing laboratory Joginder Nagar, Dist. Mandi (H.P).

(2). *Kaliphala Churna*

The drug was prepared according to the standards of GMP in the Charak Pharmacy Rajiv Gandhi Govt. Post Graduate Ayurvedic College and Hospital *Paprola*, Distt. *Kangra* (H.P.) with batch no. R-52/23 on 09/11/2023. Chemical analysis of trial formulation was done at drug testing laboratory Joginder Nagar, Dist. Mandi (H.P).

Grouping of patients

All the registered patients were randomly divided in two Groups, 15 patients in each Group.

Group - I: In this Group, patients were managed with:

Bharangyadi Kwatha - 25ml twice a day.

[12.5gm of coarse powder was boiled in 8 parts of water (100ml) and reduced to 1/4th part (25ml)].

Kaliphala Churna - 5 grams twice a day with *Madhu.*

[*Kaliphala Majja* was made into fine powder form.]

Group-II: In this Group, patients were managed with Tab. Doxofylline 400mg once a day.

Route of drug administration**:** Oral

Duration of trial: 30 days

Follow up

Follow up was done after every 15 days of commencement of therapy till completion of trial. Spirometry was also done fortnightly till completion of therapy. Investigations were done before commencement and after completion of trial.

Criteria of assessment

Patients were assessed thoroughly on the basis of various subjective and objective parameters. Assessment was done at the time of enrolment and after the completion of therapy. Grading system was adopted to assess improvement in subjective parameters. Objective parameters were computed and thus results were drawn.

Subjective criteria

- Breathlessness
- Cough
- Expectoration
- Tightness in chest
- Wheezing
- Cyanosis
- Requirement of inhaler

Table 3: Parameters and Gradation

Sr.no.	Sign and symptoms	Degree of severity	Grade
1	Breathlessness	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 5ml	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	Tightness in chest	No tightness	0
		Mild, with occasional wheezing	1
		Mild, relieved by expectoration	2
		Moderate, relieved by expectoration	3
		Severe, with wheezing throughout the day	4
5	Wheezing	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

Objective criteria

- FEV1 / FVC ratio
- Oxygen saturation
- 6 minute walk test

Data Collection and Statistical Analysis

Data was collected and recorded in clinical proforma. Statistical analysis of obtained data was done and expressed in terms of mean score/value before treatment (BT), after treatment (AT), difference of mean (BT - AT), standard deviation (SD) and standard error (SE).The results were then drawn accordingly.

Student's paired 't' test was applied for comparison of effects of drugs in Group-I and Group-II. “Sigma stat Statistical Software” was used for calculation. The results were considered significant or insignificant depending upon the value of p.

Highly significant $p < 0.001$

Significant $p< 0.05$

Insignificant $p> 0.05$

Table 4: Status of study subjects

Group	Registered	Completed trial	Drop out
I	15	15	0
II	15	15	0
Total	30	30	0

Demographic profile of study subjects

Among 30 patients maximum were of the age group 71- 80 years. Gender wise distribution revealed that maximum affected subjects were male. All the registered study subjects were married, Hindu by religion and from rural area. Maximum patients (50%) in present study were illiterate followed by primary education (30%) and matriculation (20%). All the female patients were housewives by occupation, whereas maximum male patients i.e. 36.66% were farmers and 16.66% were labourer. Majority of the patients (66.66%) in present study were from the lower socioeconomic class. Addiction wise distribution revealed that majority (53.33%) of the patients were smokers, 10% patients were alcoholics while16.66%

patients were smokers as well as alcoholics. In this study majority of the patients were either active smokers (33.33%) or ex-smokers (36.66%). Maximum number of patients i.e., 63.33% were using all (wood, coal, LPG) as source of fuel. Majority of the patients (56.66%) had reduced appetite and maximum patients (56.66%) had mixed dietary habits (62.50%). Maximum subjects (63.33%) have disturbed sleep. Majority of the patients (46.66%) followed sedentary life style, while 30% had average life style. Maximum registered patients i.e. 56.66% had regular bowel habits while 23.33% patients had irregular bowel habits and remaining 20% were having constipation and 73.33% had normal micturition. In this study majority of the patients were either active smokers (33.33%) or ex-smokers (36.66%), Majority of the registered patients were having *Kapha Vataja Prakriti* i.e. 46.66% while 30% had *Kapha-Pittaja Prakriti*.

Table 5: Effect of therapy on subjective parameters

Subjective parameters	Group	N	Mean score		% Change	Means Diff.	S.D.±	S.E.±	t-value	p-value	Sig.
			BT	AT							
Breathlessness	Gr-I	15	2.000	1.400	30	0.600	0.845	0.218	3.154	0.007	S
	Gr-II	15	2.200	1.000	54.54	1.200	0.775	0.200	8.290	<0.001	HS
Cough	Gr-I	15	2.333	1.400	39.99	0.933	0.617	0.159	14.000	<0.001	HS
	Gr-II	15	1.333	1.067	20.03	0.267	0.488	0.126	2.256	0.041	S
Expectoration	Gr-I	15	2.333	1.267	45.73	1.067	0.488	0.126	16.000	<0.001	HS
	Gr-II	15	1.600	1.133	29.18	0.467	0.737	0.190	3.500	0.004	S
Tightness in chest	Gr-I	15	1.467	1.067	27.26	0.400	0.516	0.133	3.055	0.009	S
	Gr-II	15	1.733	0.800	53.83	0.933	0.799	0.206	14.000	<0.001	HS
Wheezing	Gr-I	15	1.667	1.333	19.97	0.333	0.617	0.159	2.646	0.019	S
	Gr-II	15	2.467	0.800	67.57	1.667	0.640	0.165	13.229	<0.001	HS
Cyanosis	Gr-I	15	1.467	1.333	9.06	0.133	0.516	0.133	1.468	0.164	IS
	Gr-II	15	1.400	1.200	14.28	0.200	0.507	0.131	1.871	0.082	IS
Requirement of inhaler	Gr-I	15	1.667	1.333	19.97	0.333	0.816	0.211	2.646	0.019	S
	Gr-II	15	2.267	1.600	29.42	0.667	0.884	0.228	4.183	<0.001	HS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 6: Intergroup Comparison of Subjective Parameters

S.No.	parameters	% Relief		Diff. in % age	SD ±	SE ±	't' value	'p' Value	Sig
		Gr – I	Gr- II						
1	Breathlessness	30	54.54	24.54	0.737	0.190	2.510	0.018	S
2	Cough	39.99	20.03	19.96	0.258	0.0667	4.913	<0.001	HS
3	Expectoration	45.73	29.18	16.55	0.258	0.0667	4.025	<0.001	HS
4	Tightness in chest	27.26	53.83	26.57	0.507	0.131	3.630	0.001	S
5	Wheezing	19.97	67.57	47.6	0.743	0.192	5.227	<0.001	HS
6	Cyanosis	9.06	14.28	5.22	0.352	0.0909	0.475	0.638	IS
7	Requirement of inhaler	19.97	29.42	9.45	0.488	0.126	1.641	0.112	IS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 7: Effect of therapy on objective parameters

Objective parameters	Group	N	Mean value		% change	Mean diff	S.D±	SE±	t-value	p-value	Sig
			BT	AT							
SPO_2 (at room air)	Gr-I	15	89.267	90.000	0.82	0.733	0.704	0.182	3.556	0.003	S
	Gr-II	15	89.733	91.400	1.85	1.667	1.100	0.284	4.799	0.001	HS
FEV_1/FVC	Gr-I	15	67.867	68.000	0.19	0.133	2.875	0.742	1.000	0.334	IS

	Gr-II	15	68.400	68.600	0.29	0.200	1.805	0.466	1.382	0.189	IS
6 Minute walk test	Gr-I	15	2.800	2.467	11.89	0.333	0.676	0.175	2.646	0.019	S
	Gr-II	15	2.867	2.267	20.92	0.600	0.640	0.165	4.583	<0.001	HS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 8: Intergroup comparison of objective parameters

S.No.	Parameters	% Relief		Diff. in % age	SD ±	SE ±	't' value	'p' value	Sig
		G -I	G- II						
1.	SPO2	0.82	1.85	1.03	0.799	0.206	2.311	0.028	S
2.	FVC/FEV1	0.19	0.29	0.1	0.516	0.133	0.339	0.737	IS
3.	6 Minute walk test	11.89	20.92	9.03	0.488	0.126	1.468	0.153	IS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 9: Effect of therapy on haematological parameters

Parameters	N	Group	Mean score		% change	Mean diff.	S.D ±	SE ±	t-value	p-value	Sig
			BT	AT							
Haemoglobin	15	Gr-I	13.007	13.027	0.15	0.0200	0.907	0.234	1.871	0.082	IS
	15	Gr-II	12.333	12.353	1.62	0.0200	1.073	0.277	0.676	0.510	IS
TLC	15	Gr-I	8527.333	8495.333	0.37	32.000	728.084	187.991	3.685	0.002	S
	15	Gr-II	8360.800	8226.667	1.60	134.133	717.650	185.296	2.264	0.040	S
Neutrophil	15	Gr-I	51.733	50.267	2.83	1.467	18.109	4.676	1.866	0.083	IS
	15	Gr-II	62.867	62.267	0.95	0.600	24.133	6.231	1.790	0.095	IS
Lymphocyte	15	Gr-I	22.267	22.667	1.79	0.400	8.422	2.174	0.642	0.531	IS
	15	Gr-II	21.000	20.800	0.95	0.200	8.864	2.289	1.871	0.082	IS
Mixed	15	Gr-I	6.867	6.600	3.88	0.267	0.834	0.215	1.468	0.164	IS
	15	Gr-II	8.267	8.067	2.41	0.200	0.704	0.182	1.146	0.271	IS
ESR	15	Gr-I	27.267	26.933	1.22	0.333	14.449	3.731	2.092	0.055	IS
	15	Gr-II	25.667	24.933	2.85	0.733	26.827	6.927	2.048	0.060	IS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 10: Intergroup comparison of haematological parameters

S.No.	Parameters	% Relief		Diff. in % age	SD ±	SE ±	't' value	'p' Value	Sig
		Gr -I	Gr-II						
1.	HB (gm%)	0.15	1.62	1.47	0.0976	0.0252	1.200	0.240	IS
2.	TLC (per mm)	0.37	1.60	1.23	33.637	8.685	1.706	0.099	IS
3.	Neutrophils	2.83	0.95	1.88	3.044	0.786	1.014	0.319	IS
4.	Lymphocytes	1.79	0.95	0.84	2.414	0.623	0.949	0.351	IS
5.	Mixed	3.88	2.41	1.47	0.704	0.182	0.265	0.793	IS
6.	ESR	1.22	2.85	1.63	0.458	0.118	1.237	0.226	IS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 11: Effect of therapy on biochemical parameters

Parameters	N	Group	Mean score		% change	Mean diff.	SD±	SE±	t-value	p-value	Sig
			BT	AT							
FBS (mg/dl)	15	Gr-I	93.533	92.600	0.99	0.933	3.925	1.014	1.173	0.260	IS
	15	Gr-II	91.000	90.800	0.21	0.200	4.456	1.151	1.871	0.082	IS
TSB	15	Gr-I	0.660	0.647	2.01	0.0133	0.135	0.0349	1.468	0.164	IS
	15	Gr-II	0.760	0.740	2.63	0.0200	0.106	0.0273	1.382	0.189	IS
DSB	15	Gr-I	0.347	0.340	1.90	0.0066	0.119	0.0307	1.000	0.334	IS

	15	Gr-II	0.247	0.227	8.09	0.0200	0.0743	0.0192	1.871	0.082	IS
SGOT(IU/L)	15	Gr-I	36.200	35.533	1.84	0.667	2.651	0.685	2.000	0.065	IS
	15	Gr-II	31.000	30.800	0.64	0.200	2.699	0.697	1.871	0.082	IS
SGPT(IU/L)	15	Gr-I	26.667	26.467	0.74	0.200	1.915	0.494	1.871	0.082	IS
	15	Gr-II	26.733	26.600	0.49	0.133	1.387	0.358	1.468	0.164	IS
B.Urea(mg/dl)	15	Gr-I	31.333	30.933	1.27	0.400	3.579	0.924	2.103	0.054	IS
	15	Gr-II	32.733	32.400	1.01	0.333	3.882	1.002	2.092	0.055	IS
S.Creat(mg/dl)	15	Gr-I	0.807	0.787	2.47	0.0200	0.133	0.0345	1.871	0.082	IS
	15	Gr-II	0.807	0.780	3.30	0.0267	0.139	0.0358	1.293	0.217	IS

(S-Significant, HS-Highly significant, IS- Insignificant)

Table 12: Intergroup comparison of biochemical parameters

S.No.	Parameters	% Relief		Diff. in % age	SD ±	SE ±	't' value	'p'Value	Sig
		Gr- I	Gr-II						
1.	FBS(mg/dl)	0.99	0.21	0.78	3.081	0.796	0.914	0.369	IS
2.	TSB (mg/dl)	2.01	2.63	1.90	0.0352	0.00909	0.390	0.699	IS
3.	DSB(mg/dl)	1.90	2.13	8.09	0.0258	0.00667	0.0133	0.299	IS
4.	SGOT(IU/L)	1.84	0.64	1.2	1.291	0.333	1.333	0.193	IS
5	SGPT(IU/L)	0.74	0.49	0.25	0.414	0.107	0.564	0.582	IS
6.	B. Urea (mg/dl)	1.27	1.01	0.26	0.737	0.190	0.0667	0.790	IS
7.	S. Creat (mg/dl)	2.47	3.30	0.83	0.0414	0.0107	0.287	0.776	IS

(S-Significant, HS-Highly significant, IS- Insignificant)

Effect of therapy on subjective parameters

Breathlessness

In Group-I before treatment mean score of breathlessness was 2.000 which reduced to 1.400 after treatment, showing 30% improvement which was statistically significant (p-value 0.007). In Group-II the mean score before treatment was 2.200 which reduced to 1.000 after treatment with 54.54% improvement which was statistically highly significant (p-value <0.001).

Cough

In Group-I mean score of cough before treatment was 2.333 which reduced to 1.400 after treatment with a statistically highly significant improvement of 39.99 % (p-value <0.001). In Group-II the mean score before treatment was 1.333 which reduced to 1.067 after treatment. There was 20.03% improvement which was statistically significant (p-value 0.041).

Expectoration

Mean score of expectorations in Group-I was 2.333 before treatment and 1.267 after treatment. There was 45.73% improvement which was statistically highly significant (p-value <0.001). In Group-II the mean score before treatment was 1.600 which reduced to 1.133 after treatment with 29.18% improvement which was statistically significant (p-value0.004)

Tightness in chest

In Group-I mean score of tightness in chest was 1.467 before treatment which reduced to 1.067 after treatment with a change of 27.26% which was statistically significant improvement (p-value 0.009). In Group-II the mean score before treatment was 1.733and reduced to 0.800 after treatment showing 53.83% improvement which was statistically highly significant (p-value <0.001).

Wheezing

Mean score of wheezing before treatment in Group-I was 1.667 which reduced to 1.333 after treatment with 19.97% improvement which was significant statistically (p-value 0.019). In Group-II the mean score before treatment was 2.467 which reduced to 0.800 after treatment with a statistically highly significant improvement of 67.57% (p-value <0.001).

Cyanosis

In Group-I mean score of cyanosis before treatment was 1.467 which reduced to 1.333 after treatment with a change of 9.06 % which was statistically insignificant (p-value 0.164). In Group-II

before treatment mean score was 1.400 which reduced to 1.200 after treatment with a statistically insignificant change of 14.28% (p-value 0.082).

Requirement of inhaler: In Group-I mean score of requirements of inhaler before treatment was 1.667 which reduced to 1.333 after treatment with improvement of 19.97% which was statistically significant (p-value 0.019). In Group-II the mean score before treatment was 2.267 which reduced to 1.600 after treatment with a 29.42% statistically highly significant change (p-value <0.001).

On intergroup comparison statistically highly significant difference between two groups was observed w.r.t. cough, expectoration and wheezing (p> 0.001), while statically significant difference was observed between two groups w.r.t. breathlessness (p -value 0.018), and tightness in chest (p -value 0.001). Group-I had more advantage than Group-II in respect to cough and expectoration, while in respect to breathlessness, tightness in chest, and wheezing Group-II had more advantage than Group-I. Statistically insignificant intergroup difference was observed in cyanosis and in requirement of inhaler.

Effect of therapy on objective parameters

SPO_2: In Group I mean value of SPO_2 at room air was 89.267% before treatment which increased to 90.000% after treatment. There was 0.82% improvement which was statistically significant (p value- 0.003). Whereas in Group II mean value of SPO_2 at room air before treatment was 89.733% which increased to 91.400% after treatment with a statistically highly significant improvement of 1.85% (p value <0.001).

FEV1/FVC: In Group I mean value of FEV1/FVC was 67.867 before treatment which increased to 68.000 after treatment with a statistically insignificant change of 0.19% (p value- 0.334). In Group II mean value of FEV1/FVC before treatment was 68.400 which increased to 68.600 after treatment with a change of 0.29% which was statistically insignificant (p -value 0.189)

6 minute walk test: In Group I mean value of 6 minute walk test was 2.800 before treatment and this value after treatment was 2.467 with a statistically significant change of 11.89% (p value 0.019). In Group II mean value of 6 minute walk test before treatment was 2.867 and this value after treatment was 2.267 with a change of 20.92% which was statistically highly significant (p -value <0.001).

On intergroup comparison statistically significant difference was seen between two groups (p-value 0.028) in respect to SPO_2. The results in Group II was observed to be more effective than Group-I in respect of SPO_2. While statistically insignificant difference was seen in both the Groups in respect to FEV1/FVC and 6 minute walk test

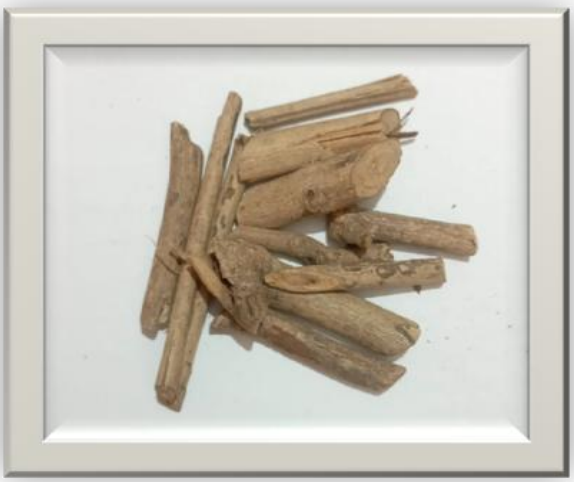
Effect of therapy on haematological parameters

All the haematological parameters remained within normal range both before and after trial in both the groups. Although statistically significant change was observed in total leucocyte count in both the groups but on intergroup comparison statistically insignificant difference was seen between both the groups.

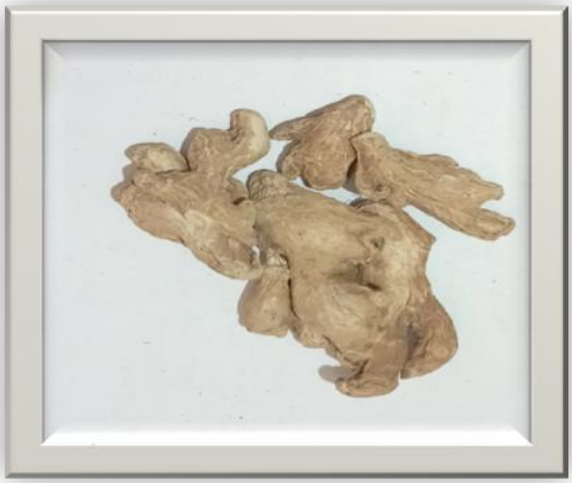
Effect of therapy on biochemical parameters

Statistically insignificant change was observed in all biochemical parameters after the therapy in both the groups. All the biochemical parameters remained within normal range both before and after therapy in both the groups.

On intergroup comparison statistically insignificant difference was observed between both the groups after completion of therapy.

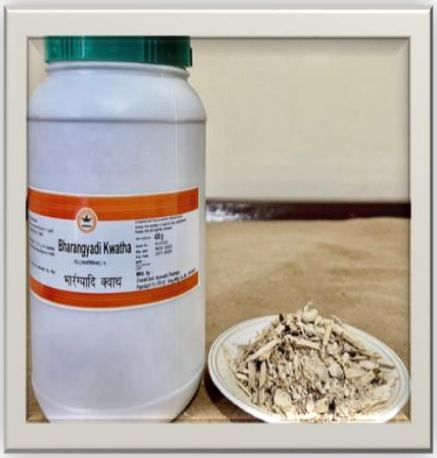


***Bharangi* Root**

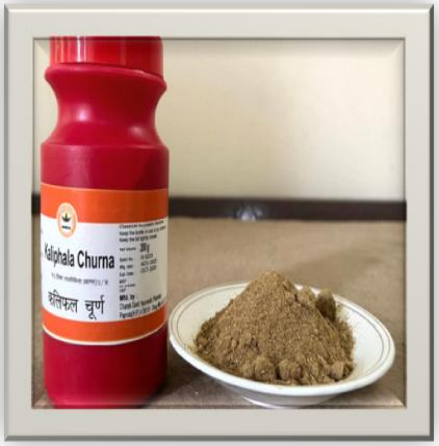


***Shunthi* Rhizome**

***Vibhitaki* Fruits**



Bharangyadi Kwatha



Kaliphala Churna

DISCUSSION

Shwasa is the disease of *Pranavaha Srotas* which gets manifested with the involvement of *Vata, Kapha Dosa, Pranavaha Rasavaha* and *Annavaha Srotas*. Pathology of *Shwasa Roga* has been described in Ayurvedic treatises that the *Prana Vayu* gets vitiated and gets obstructed in its normal course by vitiated *Kapha*, takes opposite direction and leads to manifestation of *Shwasa Roga* while the *Udbhava Sthana* is *Pittasthana.* Therefore, the drugs which are having *Vata Kapha Shamaka* properties and also do the *Shamana* of *Pitta Dosha* should be selected. In view of this, literature review was done for the selection of appropriate drug formulations, which were having properties to pacify vitiated *Vata Kapha Dosha* and to modify *Pitta Dosha*.

Probable mode of action of trial drugs

As the *Kapha* and *Vata Doshas* dominantly involve in the pathogenesis of *Shwasa Roga* and *Pitta Sthana* have been considered the *Udbhava Sthana, the* drugs which are having *Tridoshahara* properties should be taken in account. Keeping this in view, the selection of the drugs has been done. The drugs which have *Vata Kaphaghana, Vatanulomaka Deepana, Pachna* and *Pittashamaka* properties have been used to achieve *samprapti vighatana* and to prevent further progression of disease. Drugs used in the trial possess *Ushana- Virya, Katu, Tikta, Kshaya- Rasa* and *Katu, Madhur- Vipaka.*

CONCLUSION

- It was observed in present study that drugs used in Group-I had statistically highly significant results in respect of cough and expectoration but also found effective in breathlessness, tightness in chest, wheezing and requirement of inhaler. Whereas in comparison to Group-I, drug given in control group found to be more effective in breathlessness, tightness in chest, wheezing and requirement of inhaler.
- Therapies given in both the groups also found to be effective in respect of oxygen saturation and 6 minute walk test, wherein control group showed upper edge in improvement of these parameters.
- *Bharangyadi Kwatha* and *Kaliphala Churna* had a superior efficacy on symptoms like cough and expectoration, showing superior expectorant activity.
- Present study showed that, treatment given in Group-I i.e., *Bharangyadi Kwatha* (25ml twice a day) and *Kaliphala Churna* (5 grams twice a day) proved to be effective in the patients of COPD.
- No untoward effect of therapy was observed during the entire course of trial. Thus, the present study confirms the safety of *Bharangyadi Kwatha* and *Kaliphala Churna* with a promising therapeutic effect.

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