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CLINICAL STUDY TO EVALUATE THE EFFECT OF SHRINGYADI AVALEH AND KANTKARYADI SYRUP (KOFREE) IN THE MANAGEMENT OF SHWASA ROGA W.S.R. TO COPD

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ABSTRACT

"Shwasa" words mean respiration. Sanskrit origin of the word Shwasa derives its roots from 'Shwas Jivane' means the existence of life through Prana Vayu. 'Shwasa' word is used to describe the normal physiology of respiration as well as the pathological state in Ayurvedic literature. Shwasa Roga means difficulty in breathing in which cardinal symptom remains breathlessness. It is one of the most distressing diseases and is quite common. Keeping the above fact in mind the management study was planned using Shringyadi Avaleh in the dose of 10 gm oral twice a day with Luke warm water and Kantakaryadi Syrup (Kofree) in the dose of 10 ml oral thrice a day for 45 days.

KEYWORDS: Shwasa, Pranvayu, Shwasjivane.

INTRODUCTION

The breathlessness in population along with cough is more common in cases of COPD, Which can be correlated here as Shwasa Roga among all the socio-economic groups particularly the elderly in the community. This disease difficult to treat and leads to several clinical problems along with its complications. The disease has been given utmost importance in past times and is described elaborately in almost every Ayurvedic text. In Ayurveda, there are plenty of herbal medicines which may pacify the symptoms of Shwasa Roga (COPD) keeping in view this fact the present claim.

Shwasa Roga (COPD) is one of the most distressing types of disease. The world health organization (WHO) defines obstructive pulmonary disease (COPD) is a lung disease

characterized by chronic obstruction of lung airflow that interferes with normal breathing and is not fully reversible. This is in contrast to the obstruction of the variable airway. Seen in Asthma which can be reversed by drug treatment.

The airflow obstruction in COPD is due to damage to the Lung structure and destruction of lungs parenchyma (emphysema). This is normally due to smoking, but recurrent infection also contributes to the process. Despite treatment, airflow obstruction of patients of COPD is usually progressive, more recently the systemic effects of more severe COPD have been recognized, including weight loss, nutritional disturbance and abnormal skeletal muscle function. COPD is also frequently associated with and may contribute towards numerous co-existing diseases such as heart disease, osteoporosis and diabetes, which influence morbidity and mortality.

Common symptoms of COPD include chronic cough, sputum production and shortness of breath, People with COPD are at increased risk of chest infection. Some of which will be severe enough to require hospitalization. Measurements of lung function using spirometry confirm the diagnosis and help to classify the severity of the disease. Spirometry is also useful to monitor the progress of the disease and response to treatment.

In the present era, several remedies are in practice for the management of COPD. In modern science many drugs are in use and steroids are also being used to control symptoms but prolong use of these drugs may lead to side effects.

The present clinical study is planned to study the nature of the disease. Cause of the disease and management of the disease with an Ayurvedic formulation to evaluate the effect of Shringyadiavaleh and Kantkarayadi syrup.

Those patients fulfilling the criteria of inclusion were selected and managed into one group only.

The patient in this group was given Shringyadiavaleh in a dose of 10 gm BD for 45 days and Kantkariyadi syrup named as (Kofree) 10 ml TDS for 45 days. The whole research work was planned.

Aims and Objectives

- To evaluate the effects of *Shringyadiavaleh* and *Kantkariyadi* syrup named as *kofree* in the management of *ShwasaRoga* (COPD)
- To assess the course of disease based on *spirometry* during medication and to know the reversibility of the disease
- To note the change in clinical symptoms and objective parameters of the disease
- To assess the clinical safety of the drug

Selection of the patients

The patients of COPD fulfilling the diagnostic criteria were registered from OPD/IPD of R. G. G. P. G. Ayu. College and associated Hospital, Paprola Distt. Kangra (H.P.)-176115, irrespective of sex, caste, religion. Patients were selected between the age group of 35 to 75 years.

Medicine

Shringyadi Avleha was prepared at Charak Ayurvedic Pharmacy of R. G. G. P. G. Ayu. College & Hospital Parola.Whereas (Kofree syp) *Kantakaryadi syp* was prepared from Marichi Pharamacy.

Trial drug composition

a. *Shringyadi avleha*

Sr. No.	Ingredients	Botanical name	Drug quantity
1.	*Karkatshringi*	Pistachiaintegerrima	1.5kg
2.	*Sunthi*	Zinger officinale	1.5kg
3.	*Pippali*	Piper longum	1.5kg
4.	*Musta*	Cyeprusrotundus	1.5kg
5.	*Puskara*	Inularacemosa	1.5kg
6.	*Marica*	Piper nigrum	1.5kg
7.	*Sati*	Hedychiumspicatum	1.5kg
8.	*Sarkara*	Cane sugar	30kg
Kwathdravya			
9.	*Guduchi*	Tinosporacordifolia	2.5kg
10	*Vasa*	Adhatodavasica	2.5kg
11	*Bilva*	Aeglemarmelos	2.5kg
12	*Agnimantha*	Premnamucronata	2.5kg
13	*Syonaka*	Oroxylumindicum	2.5kg
14	*Patla*	Stereospremumsuaveolens	2.5kg
15	*Gambhari*	Gmelinaarborea	2.5kg

B. Content of *kantkariyadi* syrup named as *kofree (Bh.p).*

Sr. no.	Name of drug	Latin name	Dose
1.	*Kantakari*	*Solanumxanthocarpum*	50mg
2.	*Som*	*Ephedra vulgarish*	25mg
3.	*Draksha*	*Vitisvinifera*	25mg
4.	*Vasa*	*Adhatodavasica*	25mg
5.	*Madhuyasti*	*Glycyrrhizaglabra*	25mg
6.	*Karkatshringi*	*Pistachiachinnesis*	25mg
7.	*Tulsi*	*Ocimum sanctum*	50mg
8.	*Bahera*	*Terminaliabellirica*	25mg
9.	*Vanapsa*	*Viola odorata*	25mg
10.	*Sunthi*	*Zingiberofficinale*	10mg
11.	*Pipali*	*Piper longum*	10mg
12.	*Marich*	*Piper nigrum*	10mg
13.	*Talispatra*	*Abieswebbiana*	25mg
14.	*Gojihva*	*Onosmabracteatum*	25mg
15.	*Karpura*	*Cnamomumcamphora*	5mg
16.	Sugar base		Q.S

Properties of drugs used in shwasa roga

1. Shringyadi avaleha

Sr. no.	Name	Rasa	Guna	Virya	Vipaka	Dosh aghata
1.	Karkatsringi	Kasaya, Tikta	Laghu, Ruksha	Ushna	Katu	Kaph- vatashamak
2.	Sunthi	Katu	Guru, Raksha, Tikshna	Ushna	Madhur	Vata- Kaphaghana
3.	Pippali	Katu	Laghu, Snigdha	Ushna	Madhur	Vata- Kaphatara
4.	Musta	Tikta, Katu, Kashaya	Tikshna, Laghu, Rukshi	Sita	Katu	Pitta- Kaphatara
5.	Puskara	Katu, Tikta	Laghu	Ushna	Katu	Kapha- Pittahara
6.	Marica	Katu	Laghu, TikshanaUshna	Ushna	Katu	Vata – Kaphshamak
7.	Sati	Tikta, KatuKashaya	Laghu, Tikshana	Ushna	Katu	Kaph- vatashamak
8.	Guduchi	Tikta, Kashaya	Guna, Snigdha	Ushna	Madhur	Tridoshashamak
9.	Vasa	Tikta, Kashaya	Raksha, Laghu	Sita	Katu	Kaph – Pittashamak
10.	Bilva	Tikta, Kashaya	Raksha, Laghu	Ushna	Katu	Kaph- Vatashamak
11.	Agnimantha	Madhur, Tikta, Katu, Kashaya	Raksha, Laghu	Ushna	Katu	Kaph- Vatashamak
12.	Syomaka	Madhur, katuTikta, Kashaya	Raksha, Laghu	Ushna	Katu	Kaph – VataShamak

13.	Patala	Tikta, Kashaya	Laghu, Raksha	Ushna	Katu	Tridoshahara
14,	Gambhari	Madhur, Tikta, Kashaya	Guru	Ushna	Katu	Vata- Pitta Shamak (Balance)

2. Kantkariyadi syrup named as kofree (Bh.P.).

Sr. no	Name	Rasa	Guna	Virya	Vipak	Doshaghnata
1.	Kantakari	Katu, Tikta	Laghu, Ruksh, Tikshna	Ushna	Katu	Kaph-Vatahara
2.	Som					
3.	Draksha	Madhura, Kashaya	Guru, Sara, Snigdha	Sita	Madhura	Vata – Pittahara
4.	Vasa	Tikta, Kasaya	Ruksha,Laghu	Sita	Katu	Kaph-Pittashamak
5.	Madhuyasti	Madhur	Snigdha	Sita	Madhur	Vata-Pittashamak
6.	Karkatsringi	Kasaya, Tikta	Laghu,Ruksha	Ushna	Katu	Kaph-Vatshamak
7.	Tulsi	Katu,Tikta,Kashaya	Laghu, Ruksha, Tikshna	Ushna	Katu	Vatahara-Pittavardhini
8.	Bahera	Kasaya	Ruksha, Laghu	Ushana	Madhura	Kaph-pitta shamak
9.	Vanapsa	Katu,TIkta	Laghu, Snigdha	Ushna	Katu	Vata-Pittahara
10.	Sunthi	Katu	Guru, Ruksha, Tikshna	Ushna	Madhur	Vata-Kaphagna
11.	Pippali	Katu	Laghu, Snigdha, Tikshna	Ushna	Madhur	Vata-Kaphara
12.	Marich	Katu	Laghu, Tikshna	Ushna	Katu	Vata-Kaphshamak
13.	Talispatra	Madhur, Tikta, Katu	Laghu, Tikshna	Ushna	Katu	Vata-Kaphshamak Slesmapittajit
14.	Gojihva	Madhur, Tikta, Kashaya	Laghu	Sita	Madhura	Kaph-Pittahara
15.	Karpura	Tikta, Madhura, Katu	Laghu, Ruksha,	Sita	Katu	Kaph-Pittahara

Diagnosis of the patients

The patients were diagnosed on the basis of

i. Symptoms/signs
ii. Radiological criteria
iii. Spirometric criteria especially FEV1%

i. Subjective criteria

a. Symptoms

- Breathlessness on exertion
- Cough
- Expectoration
- Wheezes
- Heaviness in the chest

b. Sign

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

c. Functional criteria

- Power of exertion
- Breath holding time
- Pulse rate
- Sleep duration with posture
- Intervention with allopathic drugs.

ii. Radiographic criteria

Signs of hyperinflation

- Hyper translucent lung field
- Increased intercostals spaces
- Low flat diaphragm

- Decreased broncho-vascular markings
- Narrow or tubular heart

Signs of bronchitis

- Marked or prominent broncho-vascular markings
- Large heart.

iii. Spirometric criteria

1. Fev_1

Mild obstruction - ≥80% of predicted.

Moderate obstruction-50-79% of predicted.

Severe obstruction-30-49% 0f predicted.

Very severe obstruction-FEV1<30% of predicted or FEV1<50% plus chronic respiratory failure.

2. Fvc(L) <70%

3. Fev_1/Fvc%- <0.70

Inclusion criteria

a) Patients willing and ready to give informed consent.
b) Patients not having FEV_1<25% of predicted.
c) Age- 35 to75 years of either sex.
d) Patient fully conscious and oriented.
e) Patients fulfilling the criteria of diagnosis

Exclusion criteria

a) Patients not fulfilling the inclusion criteria.
b) Patients suffering from major systemic illness necessitating long term treatment (R.A., PTB, malignancy).
c) Poorly controlled hypertensive patients.
d) Diabetic patients.
e) Patients suffering from ACS, MI, Atrial fibrillation.
f) Patients having concomitant disorders like severe anaemia, ischaemic heart disease, congestive heart failure, acute renal failure, chronic renal failure, pneumothorax etc.
g) Patients with advanced type II respiratory failure.
h) Patients below 35 and above 75 years of age.

i) Patients who were not willing for trial.

Investigations

- Chest X-Ray (PA view).
- Spirometry.
- Routine haematological tests- Hbgm%, TLC, DLC, ESR, Absolute eosinophill count
- Biochemical investigations-FBS, B.Urea, S.Creatinine, SGOT, SGPT
- Sputum for AFB.
- ECG

Grouping of patient

Selected 22 patients were managed in one group:

- The patients in this group were given *Shringyadi Avleha* in a dose of 10 gm twice a day with lukewarm water, and *Kantkaryadi* syrup named as *Kofree (Bh.P)* in a dose of 10 ml TID.
- Duration of Trial - 45 days.

Follow up

After every 15 days i.e. on 15^{th}, 30^{th}, 45^{th} day**.** Once the trial was started, the IPD patients were evaluated daily but the OPD patients were called for follow up on every 15^{th}day to evaluate their clinical status. All the investigations like routine haematological tests, biochemical tests, chest x-ray (PA view). ECG and spirometry were done only twice, before and after the completion of a clinical trial.

Assessment criteria: Each patient was assessed based on

Subjective parameters

- Lakshana of Shwasaroga
- Clinical features of COPD

Objective Parameters:

- Staging of obstruction on the basis of spirometry

Obstruction	**Severity**
Mild obstruction	FEV1≥80% of predicted
Moderate obstruction	FEV1=50-79% predicted
Sever obstruction	FEV1=30-49%0f the predicted
Very severe obstruction	FEV1<30% of predicted or FEV1<50% plus chronic respiratory failure

OBSERVATIONS AND RESULT

22 patients were registered for the study between the age group of 35-75 years after fulfilling the criteria of selection, from the Kayachikitsa OPD/IPD of Rajiv Gandhi Government Post Graduate Ayurvedic College and Hospital, Paprola, H.P.

Demographic profile

Demographic data of 22 patients have been analyzed through percentage and is presented as below-

Total 22 patients have registered out of which 2 volunteers dropped out at the initial stage due to their reasons. Total of 20 volunteers completed the course of the therapy.

Sr. no.	Data	Maximum no. of Patients	Total no. of patients	Percentage
1	Age	56-65 years	14	64%
2	Sex	Male	20	91%
3	Habitat	Rural	20	91%
4	Religion	Hindu	22	100%
5	Marital status	Married	22	100%
6	Education	Primary	16	73%
7	Socioeconomic Status	Lower	13	59%
8	Occupation	Farmer	12	55%
9	Diet	Mixed	13	59%
10	Prakriti	Vata-Kaphaj	14	63%
11	Smoker	All Patient	22	100%
12	Types of smoking	Beedi	14	64%
13	Source of Fuel	All	9	41%
14	Bowel habit	Regular	12	55%

RESULT

The effect ShringyadiAvaleha and Kantakaryadisyp (Kofreesyp) on different parameters of Shwasaroga (COPD) were assessed based on the before treatment,post-treatment (after 15 days) after 45 days of follow up (AF) scorings “unpaired t-test” was use and statistical analysis was done using Sigma stat version 3.5 software.

Effect of trial drug on subjective criteria in patients

Sr. No.	Variables	Mean score		% relief	S.D.±	S.E. ±	't'	P
		BT	AT					
1.	Dyspnoea	1.95	0.8	58.97	0.36	0.08	14.03	<0.001
2.	Cough	1.9	0.3	84.23	0.50	0.11	14.23	<0.001
3.	Expectoration	0.75	0.10	100	0.48	1.10	5.94	<0.001
4.	Wheezes	3.55	0.30	91.54	1.37	0.30	10.56	<0.001
5.	Cyanosis	1.4	0.3	78.57	0.44	0.1	11.0	<0.001
6.	Heaviness in Chest	1	0.3	70	0.47	0.10	6.65	<0.001
7.	Oedema	0.60	0.05	83.33	0.75	0.17	3.24	<0.001

Effect of trial drug on haematological profile of patients.

Sr. No.	Variables	Mean score		% relief	S.D.±	S.E. ±	't'	P
		BT	AT					
1.	HB gm%	13.05	13.61	4.01	1.35	0.30	1.73	>0.05
2.	ESR	20.1	18.85	6.63	23.85	5.33	0.23	>0.05

Effect of trial drug on spirometric parameters

Sr. No.	Parameters	Mean score		% relief	S.D.±	S.E. ±	't'	P
		BT	AT					
1.	FVC	52.10	58.20	16.89	2.10	0.47	12.99	<0.001
2.	FEV1	60.00	71.75	19.58	7.21	1.61	7.28	<0.001
3.	FEV1/FVC%	53.50	61.30	14.57	3.23	0.72	10.77	<0.001

DISCUSSION

Disease *ShwasaRoga* is having Kapha and Vata predominance. Charak while mentioning the management explained that those diets and drugs having *Kaphavataghna. Ushna*and *Vatanulomana* properties are useful in the management of the *Shwasa Roga*.

Thus in nutshell, it can be said that various ingredients of the trial drug possess -

Chhedan, Kaphanissarak, srotoshodhan, Kapha-Vatahara&*Vatanulomna*properties which help in breaking the *samprapti* chakra of *ShwasaRoga* at various levels.

Based on these aspects, the present compound has been formulated, in which all the drugs are mostly having *vatakaphahara* and *vatanulomana* property.

CONCLUSION

Thus results of this clinical trial suggest that Shringyadiavaleha and Kofree syrup are effective and safe in the prevention and management of Shwasaroga w.s.r. to COPD. It has

no unwanted and adverse effects in the patients. It provides statistically significant results in terms of both subjective and objective parameters designed for the trial.

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