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.Dept. of Kayachikitsa in R.G.G.P.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, 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. It is currently the fourth leading cause of death worldwide and by 2020 it is expected to rise to third position. 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.
(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 criteria 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 Yogaratnakara⁴ and Shwasaghna dhuma has been taken from ‘Anubhutayoga prakaran’ of Bhaishajya Ratnavali⁵.

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. 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 Datura, 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 | 3 to 4 times in 24 hrs. without exhaustion. | Even at rest. |
| 2. Cough | No cough. | Twice in 24 hrs. without exhaustion. | 25 to 50 ml. thick. | 50 to 100 ml thick, tenacious. |
| 3. Expectoration | 5 to 10 ml. thin. | 10 to 20 ml. thin. | Moderate not relieved by expectoration. | Severe and remain through out the day. |
| 4. Heaviness in the Chest | No Heaviness. | Mild relieved by expectoration. | Three to four time in 24 hrs. | Moderate mixed. |
| 5. Wheezes | Not present. | Twice in 24 hrs. | Mild peripheral. | Present over whole lower limb. |
| 6. Cyanosis | No cyanosis. | Present on pedal and pretibial region. | Present over whole lower limb. | Moderate mixed. |
| 7. Edema | Not present. | Sleep in sitting posture (1-2 hrs.). | Present all over body. | Gross Mixed. |
| 8. Sleep duration with posture | Sleep in any posture (6-8 hrs.). | Sleep in propped up position (4-6 hrs.). | | | |
| 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. | 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. |

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

| Grade | Obstruction | Severity |
|-------|-------------|----------|
| 1     | Mild obstruction | FEV₁ ≥ 80% of predicted. |
| 2     | Moderate obstruction | 50% ≤ FEV₁ < 80% of predicted. |
| 3     | Severe obstruction | 30% ≤ FEV₁ < 50% of predicted. |
| 4     | Very severe obstruction | FEV₁ < 30% of predicted or FEV₁ < 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 FEV₁ over its pre trial value.     |
| Improved           | 20% to 39% improvement                   | 1 to 10% improvement in FEV₁ over its pre trial value.  |
| Not Improved       | < 20% improvement                        | < 1% or no change in FEV₁ over its pre trial value.     |
| Deteriorated       | Deterioration in all subjective symptoms  | Deterioration in FEV₁ 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 FEV₁(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 FEV₁(L) (p<0.05) and FEV₁/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 group II,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   |
|---------|----------------|------------|---------|-----|------|------|-----|
| 1       | Breathlessness | 3.0        | 45.83   | 0.500 | 0.125 | 11   | <0.001|
| 2       | Cough          | 3.75       | 54.98   | 0.25  | 0.0625 | 33   | <0.001|
| 3       | Expectoration  | 2.875      | 50.01   | 0.632 | 0.158 | 9.493| <0.001|
| 4       | Heaviness in chest | 2.812 | 53.35   | 0.966 | 0.241 | 6.211| <0.001|
| 5       | Wheezes        | 1.437      | 30.43   | 0.892 | 0.223 | 1.961| >0.05 |
| 6       | Cyanosis       | 2.1        | 46.85   | 1.181 | 0.295 | 3.174| <0.01 |
| 7       | Edema          | 1.25       | 20      | 0.447 | 0.111 | 2.236| <0.05 |
### Table 2: Effect of trial drug on main functional criteria of COPD w.r.t. 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_{1/2} (L)        | 0.942 1.103| 17.039   | 0.247| 0.0617| 2.600| <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| 0.3239| 1.929| <0.05 |
| 5.      | Wheezes             | 1.625 1.00 | 38.46   | 0.9160| 0.3504| 2.497| <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_{1/2} | 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 आयुर्विदिक औषधियाँ वासादि सिरप एवं श्वासच्छ धूम के प्रभाव का अध्ययन

प्रवीणकुमार शर्मा, शरद जोशी एवं ओ.एल. मेहरा

श्वास रोग का उलेख प्रायः आयुर्वेद के प्रत्येक आरोग्य-मंत्र में उल्लेख है। पुनः पुनः: कष्टपूर्वक श्वास लेना ही श्वास रोग है। प्रस्तुत संकलन में आयुर्विदिक श्वास सम्बन्धित मत का आयुर्विदिक सी..ओ.पी..डी. नामक रोग से सम्यक प्रदर्शित करते हुए आमुक रोग में आयुर्विदीय औषध योगों से होने वाले लाभ को देखा एवं उसका आंकलन किया गया। आयुर्विदिक निदान के आधार पर अतिरिक्त एवं बहिर्गंधिविभाग से श्वास के 30 रोगियों का चयन किया गया जिन्हें दो औषधियों में विभाजित किया गया। प्रथम श्रेणी का वासादि सिरप तथा द्वितीय श्रेणी का श्वासच्छ धूम दिया गया। परिणामों के आंकलन से यह सिद्ध होता है कि दोनों ही आयुर्विदीय औषधियाँ श्वास रोगों की विकृति में अत्यन्त लाभकारी हैं।