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Role of *Pippali Rasayana* in improving lung function in Chronic Obstructive Pulmonary Disease

Research Article

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Abstract

Chronic Obstructive Pulmonary Disease (COPD) is a chronic, recurrence condition, prevalent in the general population. In modern medicine, treatment modalities are aimed to reduce the frequency and severity of exacerbations of the clinical features. *Pippali rasayana* is currently being evaluated as a possible ayurvedic therapeutic option for COPD. Methodological restrictions mean that the *pippali rasayana* is not sufficiently backed up by evidence. Methods: 60 *Chronic Obstructive Pulmonary Disease* patients (30 in each group) who met the inclusion criteria were chosen for the current study. Group A (Interventional group) received treatment with *Pippali Rasayana* (2.5 gm once a day in morning), whereas Group B (control group) received treatment with Cap Placebo (Starch powder) (250 mg once a day in morning). Both groups received the medicine prescribed by pulmonologist. Results: Both groups' subjective and objective parameters significantly improved throughout the course of treatment. However, the group A showed superior improvement. Conclusion: The research provided strong evidence that *pippali rasayana*, when administered as an adjuvant therapy in conjunction with contemporary medical treatment, is more successful in lowering the symptoms of COPD.

Key Words: *Pippali, Rasayana,* COPD, PFT, Rejuvenation.

Introduction

Airflow restriction brought on by the narrowing of tiny bronchioles and the death of lung alveoli is the characteristic of chronic obstructive pulmonary disease (COPD). Dyspnea, coughing, and/or sputum production are the most typical respiratory symptoms.(1)

Currently the fourth biggest cause of mortality globally, COPD is anticipated to move up to the third spot by 2022. In 2012, more than 3 million individuals worldwide died from COPD. The burden of COPD is anticipated to rise globally in the ensuing decades as a result of population ageing and prolonged exposure to COPD risk factors (2). The projected number of COPD cases in 2010 was 384 million, with a global prevalence of 11.7 percent (95 percent confidence interval (CI) 8.4 percent -15 percent), according to Bold (Burden of Obstructive Lung Disease) and another large-scale research. (3)

In modern medicine, treatment modalities are aimed to reduce the frequency and severity of exacerbations of the clinical features. Bronchodilators, antimuscarinic medicines, methylxanthines, combination bronchodilator therapy, anti-inflammatory, inhaled corticosteroids, oral glucocorticoids, PDE4 inhibitors, antibiotics, mucolytics, etc. are among the kinds of drugs that are frequently utilized. Other therapies include bronchoscopy, oxygen therapy, ventilator assistance, lung volume reduction surgery, bullectomy, and lung transplantation. (4,5)

In *Ayurveda* the features like cough, breathing difficulties are caused due to *dushti* (vitiation) of *Pranavaha Srotas*. Although it is challenging to link COPD to a specific *Pranvaha Sroto Dushti* illness, *Tamaka Shwasa* and COPD are nearly identical (6). When *Kapha* vitiates and obstructs *Pranvayu,* causing it to move in the opposite direction—upward—and preventing it from carrying out its usual activity, the result is *Shwasa*, a *Pranvaha-Strotas* disease. *Shwasaroga* is the name given to this ailment. *(*7).

In *Ayurveda*, *Naimittik Rasayan* are mentioned for chronic illnesses. Different types of *Naimittik Rasayana* are described related to involvement of specific system (8). *Pippali Rasayan* is specifically recommended for disorders of *Pranavaha Strotas (*9).

Aims and objectives

Aims-

- Evaluation of efficacy of *Pippali Rasayana* as an adjuvant therapy on pulmonary function in patients of Chronic Obstructive Pulmonary Disease.

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Objectives

- To study the effect of *Pippali Rasayana* as an adjuvant drug with medicine prescribed by pulmonologist (Bronchodilators, antimuscarinic inhaled corticosteroids) on dyspnea, sputum formation and pulmonary function in COPD.
- To study the effect of Placebo on dyspnea, sputum formation and on pulmonary function in COPD.
- To assess how *Pippali Rasayana* and contemporary medicine compare to a placebo and modern medicine in terms of how they affect COPD patients' dyspnea, sputum production, and lung function.

Materials and methods

According to the Classical symptoms of Chronic Obstructive Pulmonary Disease diagnostic criteria, a total of 68 patients were enrolled in the current clinical study, and 8 patients withdrew from the study before it was complete. The patients had been selected from the O.P.D. & I.P.D. of Department of *Kayachikitsa* (General Medicine), Mahatma Gandhi Ayurved College, Hospital and Research Centre (DMIMSDU), Wardha, Maharashtra.

Preparation of trail drug

Raw pippali fruits were collected and correctly dried. The Pippali Rasayana was made by first making a fine powder in a pulverizer, shallow frying it with Goghrita in a stainless-steel container while using low heat, then triturating it with Panchanga Palash Kshar Udaka.

Inclusion criteria

- Patients of either gender with the age range of 30 to 70 years.
- Patients who exhibit sputum production.
- Patients of mild and moderate COPD on Spirometry criteria (given by GOLD 2006) ([10]-[11]). Global strategy for the diagnosis, treatment, and prevention of chronic obstructive pulmonary disease (COPD) 2006.

Table no. 1- Inclusion criteria for Pulmonary Function Test

Mild	Moderate
FEV1/FVC<0.70 FEV1 70-80%predicted	FEV1/FVC<0.70 FEV1=50%–69%predicted

Exclusion criteria

Lung cancer, bronchiectasis, interstitial lung disease, Congenital heart disease, Diabetes mellitus, pneumonia, lung fibrosis, pneumothorax, and tuberculosis.

Plan of study

- The study comprised the patients who met the inclusion criteria. Before being randomly selected for either the A group or the B groups using the lottery process, each patient gave their written informed consent.
- Before initiating the treatment, the patients were assessed as per the inclusion criteria.

Treatment protocol

- In group A (Interventional group), *Pippali Rasayana* 2.5gm once a day in the morning with Honey with the medicine prescribed by pulmonologist was given for 45 days and
- In group B (Control group), Cap Placebo 250 mg (Starch powder) once a day in the morning with water with the medicine prescribed by pulmonologist was given for 45 days.

Ethical clearance

The Institutional Ethical Committee (IEC) of DMIMSDU : MGACHRC/IEC/July-2020/59

Parameters for assessment

Following parameters had been taken for the assessment of the clinical study:

Subjective: (On 0 day, 15th day, 30th & 45th day of the treatment)

Table no. 2- Gradation of Dyspnea (12)

Grade	Gradation of Dyspnea
0	No breathing difficulty excluding during vigorous workout.
1	Breathlessness when speeding or walking up a slight hill.
2	During walking on flat surface Dyspnea is present.
3	Dyspnea after walking off out 100 meters on a flat surface.
4	Breathlessness while dressing or undressing.

Table no. 3- Frequency of Sputum Formation (13)

Grade	Frequency of Sputum Formation
0	Absent.
1	Only in the morning.
2	2-3 times daily.
3	Continuous.

Objective: (On 0th day & 45th day of treatment)

Pulmonary Function Test **(**On 0th day &45th day of treatment**)**

Observations

- **Age:** In this clinical trial, it was observed that out of 60 patients a maximum number of patients 22 (36.33%) were within the age group of 51–60 years.
- **Gender**: The gender-wise distribution in this study revealed that the maximum of patients (68.33%) were males.
- **Habit:** it was observed that out of 60 patients a maximum number of patients (48.33%) were smokers.

Subjective and objective parameters

Table no. 4-: Comparison of Gradation of Dyspnea between group A and group B

Group	Day 0	Day 15	Day 30	Day 45
Group A	1.16±0.64	0.80±0.76	0.33±0.47	0.10±0.30
Comparison with day 0(Wilcoxon Signed Rank Test)				
z-value	-	4.09	12.04	10.01
p-value	-	0.0001,S	0.0001,S	0.0001,S
Group B	0.50±0.50	0.46±0.50	0.46±0.50	0.40±0.49
Comparison with day 0(Wilcoxon Signed Rank Test)				
z-value	-	1.00	1.00	1.79
p-value	-	0.32,NS	0.32,NS	0.08,NS
Comparison between two groups (Mann Whitney U Test)				
z-value	3.81	1.66	1.04	2.66
p-value	0.0001,S	0.09,NS	0.29,NS	0.008,S

(S: statistically significant, NS: statistically non-significant)

Based on comparison, it was determined that the results were statistically significant at the baseline, statistically insignificant at the first and second follow-ups, and statistically significant at the third follow-up, with p-values of 0.0001, 0.09, 0.29, and 0.0008, respectively.

Table no. 5: Comparison of Frequency of Sputum Formation between group A and group B

Group	Day 0	Day 15	Day 30	Day 45
Group A	1.86±0.73	1.33±0.75	0.56±0.67	0.23±0.43
Comparison with day 0(Wilcoxon Signed Rank Test)				
z-value	-	5.75	15.27	14.54
p-value	-	0.0001,S	0.0001,S	0.0001,S
Group B	1.23±0.50	1.16±0.59	1.03±0.61	0.80±0.55
Comparison with day 0(Wilcoxon Signed Rank Test)				
z-value	-	1.43	2.69	4.70
p-value	-	0.16,NS	0.019,S	0.0001,S
Comparison between two groups (Mann Whitney U Test)				
z-value	3.42	0.63	2.75	3.90
p-value	0.0001,S	0.52,NS	0.006,S	0.0001,S

(S: statistically significant, NS: statistically non-significant)

With p-values of 0.0001, 0.052, 0.006, and 0.00001, respectively, the results were demonstrated to be statistically significant at the baseline, statistically insignificant at the first, statistically significant at the second, and statistically significant at the third follow-ups.

Table no. 6: Comparison of FVC (%) in between group A and group B

Group	Day 0	Day 45	Student's Paired t test (Between day 0 and day 45)	
			t-value	p-value
Group A	68.36±8.64	75.56±9.50	11.71	0.0001,S
Group B	71.46±8.21	72.06±8.27	1.58	0.12,NS
	t-value	**p-value**	**Comparison between two groups (Student's Unpaired t test)**	
Day 0	1.42	0.16,NS		
Day 45	1.52	0.13,NS		

(S: statistically significant, NS: statistically non-significant)

When comparing the two groups, it was discovered that there was no statistically significant difference between them at either the baseline or treatment's conclusion, with p-values of 0.16 and 0.13, respectively.

Table no. 7: Comparison of FEV1(%) in between group A and group B

Group	Day 0	Day 45	Student's Paired t test (Between day 0 and day 45)	
			t-value	p-value
Group A	65.76±11.62	72.40±10.51	9.07	0.0001,S
Group B	67.03±9.80	67.83±9.18	2.12	0.042,S
	t-value	**p-value**	**Comparison between two groups (Student's Unpaired t test)**	
Day 0	0.45	0.65,NS		
Day 45	1.79	0.07,NS		

(S: statistically significant, NS: statistically non-significant)

When comparing the two groups, it was discovered that there was no statistical difference between them at the baseline and first follow-up, with p-values of 0.65 and 0.07, respectively.

Results

Significant improvement was found in the cases between the pre- and post-treatment in various symptomatic domains in individuals of both the group.

Effect on Gradation of Dyspnea

Patients in Group-A reported relief from their dyspnea at a rate of 91.37 percent, whereas those in Group-B reported improvement at a rate of 23.07 percent. Group-A patients also felt that the improvement was considerable.

Effect on Frequency of Sputum Formation

Patients in Group-A demonstrated an improvement in Frequency of Sputum Formation of 87.63% while those in Group-B demonstrated an improvement of 34.95%. In comparison to group B, group A showed a statistically extremely significant result.

Effect on FVC (%)

In group A, FVC (%) reduced by 10.53% in group A, while in group B it was reduced by 0.83%. However, the improvement was significant in group A.

Effect on FEV1 (%)

FEV1 (%) decreased by 10.09% in group A while it decreased by 1.19% in group B. Comparing group B to group A, a statistically significant outcome was obtained.

Discussion

Shwasa is a *Pranavaha Stratos* ailment, as indicated by Acharya Charak, Sushruta, and Vagbhatt in the *Shwas-hikka Chikitsa Adhyaya*. When *Kapha* vitiates and obstructs *Pranavayu*, it goes upward instead of downward and is unable to carry out its usual function. The name for this ailment is *Shwasaroga*. *Tamak Shwas* can be correlated with Chronic Obstructive Pulmonary Disease (COPD) due to similarity in signs and symptoms (Cardinal features).

This study conducted to evaluate the effect of *Pippali Rasayana* as adjuvant therapy on pulmonary function tests in patients with Chronic Obstructive Pulmonary Disease.

Patients in the intervention group were treated with *Pippali Rasayana* 2.5 gm with honey in the morning with modern medicine treatment whereas the patients in the control group were treated with Cap. Placebo 250 mg in the morning with water and treatment prescribed by pulmonologist The treatment was given for 45 days in both the groups.

Observations showed that most COPD patients are more likely to be men, and that smoking and tobacco chewing addictions—two known risk factors for COPD—are more common in patients who are 51 to 60 years old than in those who are older. The most prevalent risk factor for COPD is found to be cigarette smoking Worldwide. Smokers have a higher prevalence of abnormalities in lung function, an increased rate of Force Expiratory Volume within 1 seeond and Force Vital Capacity decline, and higher mortality risk from COPD.

Patients were assessed for subjective as well as objective parameters like Dyspnea, sputum formation, and pulmonary function of patients before and after treatment.

Dyspnea is a *symptom* of *Vatakapha prakopa* and in the present context, *Vataprakopa* is due to *Margavrodha* due to *kapha*. The trial drugs act directly on *kapha due to its Strotoshodhana, Kapha Nissarana,* pasifying *Vata-Kapha, Rasayana*, Immuno-modulator action. and hence remove the *Avrodha* for *Vata*. Once *Avrodha* due to *kapha dosha* is removed, *Vata Dosha* starts moving in its normal *Gati* and *Marga*. Thus, the Dyspnea significantly gets alleviated. Consequently, along with the decrease in dyspnea that was shown in group A after 45 days.

In the current investigation, sputum formation was found to be a *kapha prakopa* symptom. Due to *Rasyana, Strotoshodhana*, and *Deepan-Pachan*, the experimental medications directly affect *kapha*. As a result, there is a significant reduction in the amount of sputum production. This explains the decrease in sputum production that was seen in group A after 45 days.

The FVC is reduced due to the impending obstruction of the airways mainly caused due to bronchospasm. *Pippali* possess anti-asthmatic activity which helps to relive the bronchospasm which in turn may improve the FVC in the patients of the interventional group as compared to the placebo group.

The underlying pathology involved in COPD is obstruction of airways. When the patient suffering from COPD exhales a resistance to the flow of air is observed. Hence, the amount of air exhaled in the 1st second is reduced which results in a decrease in the FEV1. The bronchodilator, mucolytic and anti-inflammatory actions of *Pippali* helps to remove the obstruction of airways which may be the reason for the improvement of FEV1 in the patients of the interventional group as compared to the placebo group. *Pippali Rasayana* possess the property of *Rasayana*, *Deepan-Pachan*, *Strotoshodhana, Vata-Kapha shamak.* And it also possess antioxidants property (14),. and, possess the Immuno-modulator action. (15)

Probable mode of action of therapy

Pippali Rasayana is indicated in the management of *Shwasa Roga.* It contains *Pippali (Pipper longum)* triturated with*Palash Kshrodak (Butea Monosprema), Go-Ghrita and Madhu* as an *Anupana*.(16)

Pippali possess *Katu Rasa, Laghu, Snigdha, Tikshna Guna, Anushnasheeta Virya, Madhura Vipaka, Kaphavata Shamak*, and *Rasayan*, which may aid in improving lung function in COPD. *Palash* has *Tikta, Kashay, Katu Rasa, Laghu, Snigdha Guna, Katu Vipak,* and *Ushna Virya,* which may be used to pacify vitiated

Vata-Kapha. The medication reaches *Sukshma Strotas* because of *Ushna Virya*, which helps to clear the *Strotorodh* due to *Kapha* and prepare them for *Vata* smooth operation. These properties may help in alleviating *Pratyatma Lakshana* (Cardinal Feature) of Chronic Obstructive Pulmonary Disease i.e. chronic cough, dyspnea, sputum formation, and also have anti-asthmatic activity, anti-inflammatory activity (17).

Go-Ghrita has *Madhura Rasa, Snigdha, -Guru Guna, SheetaVirya* and *Madhura Vipaka* and *Tridosha Shamaka, Yogavahi, Rasayana, Agnidepana* which may help in alleviating the symptoms such as dyspnea by pacifying the vitiated *Vata Dosha,* and its property helps in strengthen the *Pranavaha Strotsas.*

Anupan was given as *Madhu*. It has the following characteristics: *Sheeta Virya, Katu Vipaka, Laghu-Rukshaguna, Madhur-Kashaya Rasa,* and *Tridoshahara*. *Lekhana* may have reduced the production of sputum by soothing vitiated *Kapha Dosha*, and its ability to strengthen the *Pranavaha Strotas* as well as have immune-modulatory, antimicrobial, and anti-inflammatory effects. (18)

Conclusion

The goal of the current study was to assess *Pippali Rasayana* effectiveness on pulmonary function tests in individuals with chronic obstructive pulmonary disease when used as an adjuvant medication.

Prior to and following treatment, patients were evaluated for subjective as well as objective indicators like dyspnea, sputum production, and pulmonary function. Observations showed that most COPD patients are more likely to be men (68.33%) than women (28.33%), and that chewing, and smoking are the two most common addictions among patients (48.33%) and patients with COPD (28.33%), respectively.

According to statistics, dyspnea significantly decreased in both groups, although sputum output increased non-significantly in the placebo group. While FVC group A exhibited statistically significant improvement, FEV1 in both groups showed a statistically significant improvement. Although there was no statistically significant difference between the groups when it came to dyspnea and sputum production, it did exist for FEV1 and FVC.

Therefore, it can be inferred that *Pippali Rasayana* is more effective at lowering the symptoms of COPD when used as an adjuvant therapy in addition to modern medical treatment.

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