

A clinical study to evaluate the efficacy of Pippali Rasayana in certain respiratory disorders

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ABSTRACT : Two million people die per year due to pulmonary tuberculosis all over the world. The 15 million new cases are diagnosed every year in India, of which 90% have pulmonary tuberculosis. Chronic bronchitis is the second most common lung disorder after pulmonary tuberculosis equally prevalent in rural and urban areas. Similarly nearly 6% population suffers from Bronchial asthma in India. Respiratory system is one such in human body which gets affected from a variety of infections and condition may become worse when body lacks sufficient immunity. Though drugs like corticosteroids, bronchodilators, anti tubercular therapy offer relief but may have many side effects. In Ayurveda answer to these problems is Rasayana therapy. Role of Rasayana therapy with recent advancement can be adjusted in terms of immuno modulatory, cytoprotective, genoprotective, adaptogenic, stress reliever actions etc. In this study a textual formulation. 'Pippali Rasayana' was given for a period of 45 days after Koshtha shodhana to 15 patients diagnosed with common respiratory diseases. Control group of 12 patients was observed as such while taking their respective medications. A remarkable improvement was noted in clinical features as well as general conditions of these patients indicating the beneficial role of 'Pippali Rasayana' as adjuvant.

Key words : Pulmonary Tuberculosis, Chronic Bronchitis, Bronchial Asthma, Pippali Rasayana.

INTRODUCTION

Absolute health is not mere the absence of disease but a state of physical, mental and social well being. In the present era there are various challenges to health like stress, anxiety, depression, reduced natural immunity, exposure to pollution causing increased susceptibility to infections and serious illness.

Respiratory system is one such in human body which gets affected from a variety of infection and the condition may become worse when body lacks sufficient immunity to fight foreign invasion. Pulmonary tuberculosis remains one of the killer diseases in the world. It has been described as 'King of Disease' in the Vedas and is mentioned in *Charaka Samhita*, *Sushruta Samhita* as *Rajyakshma*^{1,2}. Co-infection with HIV/AIDS, Multi drug resistant tuberculosis (MDRTB), negligence towards nutrition and health, drug induced toxicity etc., together these factors contribute in deteriorating the picture^{1,3}.

Similarly Bronchial Asthma which is correlated with the description of disease *Tamaka shwasa*^{4, 5, 6} in *Ayurvedic* texts is provoked by specific allergens, recurrent respiratory tract infections and psychological factors like stress⁷. Another commonest respiratory disease Chronic Bronchitis presents with morbidity, mortality and frequency of respiratory illness. It can be

well correlated with *Shwasa roga* mentioned in *Ayurvedic* texts.

Lots of advances have been achieved through modern medicine in combating these diseases e.g. anti tubercular therapy, advanced antibiotics, corticosteroids, bronchodilators etc. All these fight the disease and offer relief but patients with weak immune status due to recurrent infections, malnutrition, drug toxicity, disease chronicity, stress factors etc. become prone to further infections and exacerbations of disease hampering their life quality. Simultaneously increasing incidence of resistance and high cost of therapy are common problems³.

In view of above facts the present trial was undertaken to evaluate the efficacy of the Ayurvedic formulation-*Pippali*^{8, 9, 10} *Rasayana*¹¹ mentioned in *Charak Samhita* in diseases of Respiratory system as an adjuvant.

MATERIAL AND METHODS

In the present study, total 32 patients with signs and symptoms suggestive of commonest respiratory disorders i.e. *Rajyakshma* (Pulmonary tuberculosis), *Tamaka shwasa* (Bronchial asthma), *Shwasa roga* (Chronic bronchitis) were selected from OPD and IPD of R.G. Govt. P.G. Ayu. College and Hospital Paprola (H.P). Out of 32 registered patients, 27 patients completed the trial. In these 27 patients there were 9 patients each of the above mentioned diseases. They were studied in double trial groups having 15 patients in group I and 12 patients in group II.

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Inclusion Criteria :

- ◆ Patients who were willing to take trial drug.
- ◆ Patients falling in the age group of 20-70 years.
- ◆ Patients suffering from above mentioned respiratory diseases.
- ◆ Only uncomplicated cases diagnosed on the basis of signs and symptoms were considered.
- ◆ Cardinal signs and symptoms taken in inclusion criteria were features like frequency and duration of exacerbation, chest tightness, cough, wheezing, dyspnoea and necessity of modern medication.
- ◆ Other criteria were based on features related to degraded quality of life like non feeling of wellbeing, weight loss, fatigue, loss of appetite and sleep.
- ◆ Objective criteria of inclusion were the routine haemogram, chest x-ray PA view, urine examination, ECG as per requirement.

Exclusion Criteria :

- ◆ Patients not fulfilling the inclusion criteria.

Method of study : The diagnosed patients fulfilling the inclusion criteria were subjected to the clinical trial. All the registered patients were managed in a double trial group. Trial group-I patients were given the trial drug as an adjuvant along with allopathic drug which the patients were already taking. Trial group-II patients were not given the trial drug but observed as such while taking the respective drug. After registration, an elaborated history was taken and detailed physical and systemic examination was conducted. In addition to it *Srotas Pariksha*, *Ashtavidha Pariksha* and *Dashavidha Pariksha* were also carried out. In every case the probable pathogenesis was explored depicting all the *samprapti ghatakas*. Laboratory investigations like routine blood tests, urine routine and microscopic examination and chest x-ray (PA view) were carried out in the beginning and at the completion of trial.

Drug and dose : *Pippali Rasayana*¹¹ prepared from *Palash Kshara bhavit Pippali*¹¹ was given in powder filled capsules form in a dose of 2.5 gm per day. Prior to its intake *koshthashuddhi* was advocated. For this *Haritakyadi Churna*¹² in a dose of 3-4 gm at bed time was given for 3-7 days according to the type of *koshtha* of the patient.

Duration of trial : 45 days.

Instruction to the patients : The patients were instructed to take luke warm water and to avoid exposure to polluted environment, cold weather, smoking, spicy and fried food.

Assessment Criteria :

Assessment of the effects of therapy was done on the basis of various subjective and objective parameters. Patients were thoroughly assessed after, every 15 days of commencement of therapy and after completion of trial period i.e. 45 days. Routine haematological, urine examination and chest X-ray (PA view) were done before and after completion of trial. Various symptoms were awarded grades from 0-4 according to severity. Following were criteria of assessment.

Subjective parameters (Related to respiratory signs and symptoms) :

1. Frequency of exacerbations
2. Duration of exacerbations
3. Tightness
4. Cough
5. Wheezing
6. Sputum
7. Dyspnoea on exercise
8. Nocturnal dyspnoea
9. Necessity of modern medication

Subjective parameters (Related to degraded quality of life) :

1. General feeling of well being
2. Ability to work
3. Fatigue
4. Appetite
5. Digestion
6. Mental feeling of well being
7. Sleep
8. Weight gain

The following categorization was done on the basis of above mentioned subjective and objective features -

- ◆ **Marked improvement :** 50% and above improvement in subjective & objective symptoms from its pretrial value.
- ◆ **Improved :** 30- 49% improvement in subjective & objective symptoms from its pretrial value.
- ◆ **Mildly improved :** <30% improvement in subjective & objective symptoms from its pretrial value.
- ◆ **Deteriorated :** Deterioration of all above subjective and objective parameters over its pretrial value.

OBSERVATIONS AND RESULTS

A total 32 patients were registered in the present study, but 27 patients completed the trial and five patients failed to complete the trial and were considered drop out. Demographic observations were made on 32 patients and effects of the therapy were carried out in 27 patients. In the present study maximum number of patients i.e.53.12% belonged to 46-70 years age group with more male population (56.3%). Majority of patients belonged to rural habitat (78.17%) and were illiterate (34.4%) belonging to poor socio-economic status(46.9%).Majority of patients were smokers (56.3%) and source of fuel used was wood in majority of patients household (65.6%).Most of the patients were having *Vata Kaphaj deha prakriti* (65.6%) and *Krura koshttha* (40.6%).

Effect of therapy on most of the criteria related to degraded quality of life showed marked percentage improvement in trial group-I as compared to trial group-II ($p<0.001$) (Table no.1).While assessing the

functional criteria related to respiratory signs and symptoms, features like cough, wheezing, sputum, dyspnoea on exertion, nocturnal dyspnoea showed good percentage improvement in trial group-II as compared to trial group-I ($p<0.05$) while features like frequency of exacerbation, duration of exacerbation etc. showed mild percentage improvement in trial group-I as compared to trial group-II ($p>0.05$) (Table no.2). Increase in Hb% and reduction in ESR showed statistically significant result after the therapy in trial group-I as compared to trial group-II ($p<0.05$), (Table no.3). The overall effects of therapy were encouraging as in trial group-I, out of 15 patients 86.7% were moderately improved and 13.3% were markedly improved as compared to trial group-II where out of 12 patients, 33.3% were moderately improved and 66.6% were mildly improved (Table no. 4). Results of the x-ray chest (PA view) taken during the trial period showed improvement in both the trial groups. Urine analysis was also within normal limits in both the trial groups.

TABLE NO.1 : COMPARATIVE STUDY OF CRITERIA OF RASAYANA EFFECT IN TRIAL GROUP - I & II :

Sr. No.	Features	Trial Group - I					Trial Group - II					I vs II 't'	p
		Mean score		% Relief	SD±	t	Mean score		% Relief	SD±	t		
		BT	AT				AT	BT					
1	General feeling of well being	4	1.26	68.3	0.5936	17.83	3.5	1.6	53.4	0.288	0.27	4.32	<0.001
2	Ability to work	4	1.33	66.6	0.4879	21.16	3.6	1.5	56.8	0.668	10.7	6.4	<0.001
3	Fatigue	3.77	1.2	67.8	0.5163	19	3.2	1.5	51.2	0.492	10.7	4.35	<0.001
4	Appetite	3.66	1.93	47.2	0.4577	14.66	3.4	2.5	26.8	0.792	4.0	3.38	<0.01
5	Digestion	3	1.26	57.7	0.4577	14.66	2.6	1.5	43.7	0.577	7	2.85	<0.01
6	Mental feeling of well being	3	1.4	53.	0.5070	12.22	2.8	1.4	50	0.514	9.5	2.52	<0.05
7	Sleep	2.66	1.06	60	0.5070	12.22	2.1	1.08	50	0.668	5.6	2.68	<0.05
8	Weight gain	4	1.06	71.6	0.3518	31.55	3.25	2.1	33.3	0.900	4.1	9.37	<0.001

TABLE NO. 2 : COMPARATIVE STUDY OF FUNCTIONAL CRITERIA (PERCENTAGE WISE) IN THE TRIAL GROUP - I & II :

Sr. No.	Features	Trial Group - I					Trial Group - II					I vs II 't'	p
		Mean score		% Relief	SD±	t	Mean score		% Relief	SD±	t		
		BT	AT				AT	BT					
1	Frequency of exacerbation	3	1	66.6	0.4714	13.416	3.125	1.375	56	0.7071	7	0.893	>0.05
2	Duration of exacerbation	3	1.1	63.3	0.3162	8.281	2.125	0.75	64.7	0.7440	6.40	2.04	>0.05
3	Tightness in chest	3	1.2	60	0.4216	13.5	3	1.125	62.5	0.3535	15	0.37	>0.05
4	Cough	3.06	0.33	89.1	0.4577	23.127	2.833	0.666	76.4	0.3892	19.2	5.04	<0.001
5	Wheezing	2.9	0.7	75.8	0.4216	16.5	2.375	0.5	78.9	0.6408	10.1	2.22	<0.05
6	Sputum	2.33	0.2	91.4	0.6399	12.91	1.833	0.416	77.2	0.7929	6.18	2.67	<0.05
7	Dyspnoea on exertion	2.93	0.666	79.5	0.4879	18.52	2.416	0.666	72.4	0.6215	9.75	2.7	<0.05
8	Nocturnal dyspnoea	2.7	0.8	70.3	0.8755	6.86	2.375	0.75	68.4	1.060	5.30	2.22	<0.05
9	Necessity of modern medication	2.6	1	65.3	0.6749	7.964	3	0.875	70.8	0.8345	8.82	1.23	>0.05

TABLE NO. 3 : COMPARATIVE STUDY OF HEMATOLOGICAL PROFILE IN PERCENTAGE IN TRIAL GROUP-I & II :

Sr. No.	Variable	Trial Group - I				Trial Group - II				I vs II 't'	Two tailed 't'		
		Mean score		% Relief	SD±	t	Mean score		% Relief			SD±	t
		BT	AT				AT	BT					
1	Hb% (gm%)	10.18	11.2	10.20	0.4154	9.69	10.55	10.81	5.21	0.3605	5.28	2.29	<0.05
2	ESR (mm in 1 st hr.)	46.4	14.7	68.24	22.06	5.55	54	19.16	19.16	30.38	3.97	1.42	<0.05
3	FBS (mg%)	95.46	81.3	14.80	7.405	7.39	86.5	86.6	3.56	3.315	3.22	4.76	<0.001

TABLE NO. 4 : COMPARATIVE STUDY OF OVERALL RESULTS IN TRIAL GROUP-I AND II.

Results	Trial group - I		Trial group - II	
	No. of patients	%	No. of patients	%
Markedly Improved	2	13.33	0	0
Improved	13	86.66	4	33.33
Mildly Improved	0	0	8	66.6
Deteriorated	0	0	0	0

DISCUSSION

Features like appetite, digestion, weight gain improved due to improved nutrition at the cellular level by *deepan-pachan* and *agnivardhan* properties of *Pippali Rasayana*. Improved nutrition to each and every body tissue results in improvement in features like general and mental feeling of well being, ability to work and fatigue.

Pippali Rasayana through *Vata-kapha* pacifying, *srotoshodhan* and *Kapha nissarana* properties makes the pathway clear for proper circulation of *Vata* thus relieving various respiratory signs and symptoms.

CONCLUSION

On the basis of this study, it can be concluded that trial drug, "*Pippali Rasayana*" is very much effective in the management of *respiratory diseases as an adjuvant*. No untoward effects of the drugs were noted during the trial and follow-up period.

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हिन्दी सारांश

प्राणवह स्रोतस दुष्टिजन्य विकारों में पिप्पली रसायन के प्रभाव का अध्ययन

दीप्ति बिष्ट, वाय. के. शर्मा एवं बी. एल. मेहरा

राज्यक्ष्मा व्याधि से प्रतिवर्ष बीस लाख लोगों की मृत्यु होती है। भारतवर्ष में ६ प्रतिशत लोग तमकश्वास से पीड़ित हैं। प्राणवह स्रोतस विभिन्न संक्रमणों से ग्रसित होता है, और विशेष रूप से अल्प व्याधि प्रतिकारक्षमता वाले लोगों में यह अधिक प्रभावित होता है। आयुर्वेदोक्त रसायन चिकित्सा इन व्याधि में उपयुक्त है। प्रस्तुत अध्ययन में आयुर्वेदोक्त पिप्पली रसायन प्राणवह स्रोतस विकारों से पीड़ित १५ रुग्णों में ४५ दिनों तक प्रयुक्त किया गया। जबकि नियंत्रण समूह के १२ रुग्णों को सामान्य चिकित्सा जारी रखी गई। पिप्पली रसायन चिकित्सित रुग्णों में लाभकारी परिणाम देखे गये।

