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Randomized Controlled Clinical Trial to Study the Efficacy of *Triphala Pippali Churna* in the management of *Kaphaj Kasa* with special reference to Chronic Bronchitis

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ABSTRACT

Respiratory illness is one of the most important & challenging area of general practice. *Kasa* is the disease of *Pranavaha strotas*. It may develop as an independent disease, symptom or complication. *Kaphaj Kasa* is one of the conditions in which vitiated *Kapha Dosha* causes *Margavarodha* to the *Pranavata Strotas* producing *Ghana* (thick sputum), *Snigdha* (slimy), *Bahala* (profuse sputum) and *Sandra Kapham* (viscid sputum). *Kaphaj Kasa* displays many features in common with the collections of signs and symptoms that are specially diagnosed with Chronic bronchitis. It is characterized by cough associated with sputum for at least 3 consecutive months for more than 2 successive years. Aim: To study the efficacy of *Triphala Pippali Churna* in the management of *Kaphaj Kasa* with Special reference to chronic Bronchitis. Materials and Methods: A total 100 patients of the age group 16-60 years presenting with signs and symptoms of *Kaphaj kasa* w.s.r to chronic bronchitis were selected randomly from OPD of the department of *Shalakyatantra*. The 50 patients of trial group were treated with *Triphala Pippali Churna* and 50 patients of control group were subjected to *Vasavleha*. Results: *Triphala Pippali Churna* is more effective as compared to *Vasavaleha* in *Kaphaj kasa*. Conclusion: *Triphala Pippali* is an effective, safe and potent treatment of *Kaphaj kasa* w.s.r. to Chronic bronchitis.

Key Words *Ayurveda, Kaphaj kasa, Chronic bronchitis, Triphala Pippali churna, Vasavaleha*

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INTRODUCTION

Respiratory illness is one of the most important & challenging area of general practice. Disease *Kasa* is found allthe globe & in all age groups. Our ancient system of medicine has

described all the characteristics of the disease *Kasa*.

Kasa is the disease of *Pranavaha strotas*. It may develop as an independent disease, symptom, or complication¹. *Kaphaj Kasa* is one of the conditions in which vitiated *Kapha Dosha* causes

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Margavarodha to the *Pranavata Strotas* producing *Ghana* (thick sputum), *Snigdha* (slimy), *Bahala* (profuse sputum) and *Sandra Kapham* (viscid sputum). The *Hetu* of the disease is caused due to consumption of *Guru Ahara*, *Abhishyandi Ahara*, *Madhura Ahara*, *Snigdha Ahara* and *Viharaja Hetu* include *Swapna vichehsta*. In the disease the *Vata* and *Kapha* are the two *Doshas* involved in the *Samprapti* of *Kaphaj kasa*. *Kaphaj Kasa* displays many features in common with the collections of signs and symptoms that are specially diagnosed with Chronic bronchitis².

Chronic Bronchitis is characterized by cough associated with sputum for at least 3 consecutive months for more than 2 successive years. The initial symptoms are repeated attacks of productive cough which shows a steady increase in severity during the winter & rainy seasons and present all the year round with recurrent respiratory infections.

As *Pranavaha Strotas* conveys *Prana*, any disease affecting this *Strotas* has to be treated with priority³. *Kaphaj Kasa* may not be life threatening but increasingly annoying and irritating to the individual in their routine activity. When neglected it may lead to a series of complications later⁴.

In recent years, there has been surprisingly increase of incidence related to Respiratory system because of the exposure to both active and passive smoke, air pollution, occupational hazards⁵.

Prana and *Apana* or to say breathing out and breathing in are the sine que non- phenomenon of life. To and fro movement of air through the *Pranavaha srotas* is the vital sign of *Prana*, the normalcy of which suggests health. The abnormality of respiration indicates disease, and its cessation marks death. This unique sign of life is affected in the disease *Kasa*.

Cough is the fifth most common symptom for which patients seek care. Americans spend more than \$600 million annually on over-the-counter sale and prescription sale of medications for cough. Cough occurs in association with acute upper respiratory infection, acute pharyngitis, acute bronchitis, and chronic sinusitis, all of which rank among the top 10 reasons for visiting family physicians. Cough is seen associated with many of the systemic disorders. The attack rate of cough in children is very high leading to morbidity and mortality. With the growing knowledge about respiratory infections, the cough is clearly defined and differentiated from other illness presenting with cough. The leading causes of recurrent attack of cough in children throughout the world is increased environmental exposure, host derived factors may be non-immunological or related to host immune-deficiency⁶.

Triphala Pippali Churna is mentioned in *Sharangdhara Samhita* in the treatment of *Kasa*. No research Study on *Triphala Pippali Churna* in the management of *Kaphaj Kasa* was conducted yet. Hence a clinical study will be planned to

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prove efficacy of it in the management of *Kaphaja Kasa*.

In Modern system of medicine Chronic Bronchitis is treated with bronchodilators and corticosteroids symptomatically⁷. But long-term usage of these drugs will show adverse effects like loss of bone mineral density, weakened immune system, dryness of mouth, irritated throat, loss of appetite and anxiety. so, there is a serious and urgent need of better management and safe drugs without the adverse effects. *Ayurveda* had not only provided at wide range of drugs but also provided the various preventive measures to be followed while cured the disease⁸.

Rationale of Study:

Kaphaj Kasa (Chronic bronchitis) is a condition inflammation (swelling) and irritation of the bronchial tubes. Bronchial tubes are the airways that carry air to and from the air sacs in your lungs. The irritation of the tubes causes mucus to build up. The mucus and the swelling of the tubes make it harder for your lungs to move oxygen in and carbon dioxide out of your body. Although treatment like steroids, anti-inflammatory, bronchodilator medicines are available which causes dilation of the bronchial tubes but they have some limitation and side effects. Therefore, there is need to look for more efficacious agents with lesser side effects. *Triphala Pippali churna* and *Vasavleha* are easily available in market and their cost is also economical. In *Ayurveda* there is detailed information of *Kaphaj Kasa* (Chronic bronchitis) and its management in various *Ayurveda* texts.

AIM

To study the efficacy of *Triphala Pippali Churna* in the management of *Kaphaj Kasa* with Special reference to Chronic Bronchitis.

OBJECTIVES

1. To study the efficacy of *Triphala Pippali Churna* in the management of *Kaphaj Kasa*.
2. To compare the efficacy of *Triphala Pippali Churna* and *Vasavleha* in the management of *Kaphaj Kasa*.

MATERIAL AND METHODS

Total 100 patients of the age group 16-60 years presenting with signs and symptoms of *Kaphaj kasa* w.s.r to chronic bronchitis were selected randomly from OPD and IPD of the department of *Shalakyatantra*) within inclusion criteria and were treated in two groups. The 50 patients of trial group were treated with *Triphala Pippali Churna* and patients of control group in similar number were subjected to *Vasavaleha*.

Criteria for selection of patients:

Diagnostic Criteria: Patients were diagnosed which were having signs and symptoms of *Kaphaj kasa* given in *Ayurveda* and chronic bronchitis in modern literature as like *Kasavega* (coughing), *Nissthivan ghanakapham* (Productive cough), *Peenasa* (running nose), *Swashkashtata* (dyspnoea) and *Agnimandya* (loss of appetite)

Inclusion criteria:

- Patients having classical signs and symptoms of *kaphaj kasa* w.s.r Chronic bronchitis

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- Patients of age between 16-60 years irrespective of religion, socio-economic status and gender.
 - Patients of known case of Tuberculosis, cancer of bronchus, pleurisy, lung abscess, pneumonia, pulmonary oedema resulting from cardiac & renal disease.
 - Patient suffering from systemic disease like uncontrolled HTN, Diabetes Mellitus Cancer, Leprosy, T.B, Cardiac disorder.
- Exclusion criteria-**
- Patients not willing for trial and follow up.
 - Patient having Viral and Bacterial conjunctivitis.

Table 1 Assessment criteria

Parameters	Symptoms	Grade
Kasavega (coughing)	Absent (No coughing or negligible; not affecting daily activities.)	0
	Mild (occasional coughing; noticeable but not significantly impacting daily life.)	1
	Moderate (frequent coughing; pronounced and somewhat disruptive)	2
	Severe (persistent coughing; significantly impacting daily life)	3
Peenasa (Running Nose)	Absent (No running nose; not affecting daily activities)	0
	Mild (Occasional running nose; noticeable but not significantly impacting daily life)	1
	Moderate (Frequent or persistent running nose; interrupts daily activities to a moderate extent.)	2
	Severe (Constant and heavy runny nose; significantly hinders daily life and may require urgent attention.)	3
Nisthivan Ghanakapham (Productive Cough)	Absent (No productive cough; no impact on daily activities.)	0
	Mild (Occasional, light productive cough; noticeable but not disruptive.)	1
	Moderate (Frequent or persistent productive cough; interrupts daily activities to a moderate extent.)	2
	Severe (Intense and constant productive cough; significantly hinders daily life and may require urgent attention.)	3
Shwaskashyata (Dyspnea)	Absent (No difficulty breathing; no impact on daily activities.)	0
	Mild (Occasional, mild difficulty breathing; noticeable but not disruptive.)	1
	Moderate (Frequent or persistent difficulty breathing; interrupts daily activities to a moderate extent.)	2
	Severe (Intense and constant difficulty breathing; significantly hinders daily life and may require urgent attention.)	3
Agnimandhya (Anorexia)	Absent (No anorexia; normal appetite.)	0
	Mild (Occasional, mild loss of appetite; reduced but not significantly disruptive.)	1
	Moderate (Frequent or persistent loss of appetite; interrupts daily activities to a moderate extent.)	2
	Severe (Intense and constant loss of appetite; significantly hinders daily life and may require urgent attention.)	3

Follow ups: 7th, 14th, 21st day of treatment.

The graded values mentioned in the Table No.1 were later totally and individually scored and assessed statistically to find out the rate of effect of treatment. Treatment protocol was given as discussed in Table No.2. The age, gender, occupation, habitat wise distribution of patients

with socioeconomic status was also recorded and assessed statistically. The effect of treatment in each group was assessed separately by analysing the pre-treatment and post treatment data, scores, and values.

The comparison of the effect of therapy of two groups done by statistical analysis. All the above
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ingredients are taken in powder form and in equal quantity and mixed properly in equal quantity.

Table 2 Ingredients of drug and preparation of *Triphala Pippali Churna*

<i>Pippali</i>	1 Part
<i>Amlaki</i>	1 Part
<i>Bibhitak</i>	1 Part
<i>Haritaki</i>	1 Part

Table 3 Drug Regimen

Subject	Group A	Group B
Number of patients	50	50
Age group	16-60 yrs	16-60 yrs
Drug name	<i>Triphala Pippali Churna</i>	<i>Vasavaleha</i>
Dose of drug	4 gm/ day 500 mg every 2 hourly.	10 gm BD
<i>Anupan</i>	Honey	lukewarm water
Route of administration	Oral	Oral
Duration	3 weeks	3 weeks
Follow up	0 th , 7 th , 14 th , 21 st	0 th , 7 th , 14 th , 21 st

Data thus collected during the study, summarized and statistically analyzed as per protocol.

Table No.4: Statistical Analysis for Group A (Trial Group) for subjective criteria by Wilcoxon Signed Rank test-

Sr No	Variables	Number of Pairs (N)	Z value	BT Mean	SD	AT Mean	SD	P
1.	<i>Kasavega</i> (coughing)	50	-6.299	2.72	0.45	0.58	0.50	<0.0001 Highly significant
2.	<i>Peenasa</i> (Running Nose)	50	-6.833	2.96	0.20	0.04	0.20	<0.0001 Highly significant
3.	<i>Nisthivan Ghanakapham</i> (Productive Cough)	50	-6.450	3.00	0.00	0.30	0.46	<0.0001 Highly Significant
4	<i>Shwaskashtata</i> (Dyspnea)	50	-6.291	2.72	0.45	0.56	0.50	<0.0001 Highly Significant
5	<i>Agnimandhya</i> (Anorexia)	50	-6.833	2.96	0.20	0.04	0.20	<0.0001 Highly Significant

Table 5 Statistical Analysis for Group B (Control Group) by Wilcoxon Signed Rank test- (subjective criteria)

Sr No	Variables	Number of Pairs (N)	Z value	BT Mean	SD	AT Mean	SD	P
1.	<i>Kasavega</i> (coughing)	50	-6.551	2.72	0.45	0.94	0.24	<0.0001 Highly significant
2.	<i>Peenasa</i> (Running Nose)	50	-6.944	2.96	0.20	0.96	0.20	<0.0001 Highly significant
3.	<i>Nisthivan Ghanakapham</i> (Productive Cough)	50	-6.551	2.72	0.45	0.94	0.24	<0.0001 Highly Significant
4	<i>Shwaskashtata</i> (Dyspnea)	50	-6.693	2.98	0.14	1.08	0.40	<0.0001 Highly Significant
5	<i>Agnimandhya</i> (Anorexia)	50	-6.458	2.72	0.45	0.76	0.43	<0.0001 Highly Significant

Table 6 Statistical analysis in between the trial and control group subjective parameters (by Mann Whitneys U test)

Parameters	Group	Mean Rank	Sum of ranks	Z value	Mann-Whitney U	p value
<i>Kasavega</i> (coughing)	Trial	57.85	2892.50	-3.023	882.50	0.003 S
	Control	43.15	2157.50			
<i>Peenasa</i> (Running Nose)	Trial	73.04	3652.00	-8.938	123	<0.0001 S
	Control	27.96	1398.00			

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<i>Nisthivan Ghanakapham</i> (Productive Cough)	Trial	69.65	3482.50	-7.387	292.5	<0.0001 S
	Control	31.35	1567.50			
<i>Shwaskashtata</i> (Dyspnea)	Trial	56.12	2806.00	-2.377	969	0.017 S
	Control	44.88	2244.00			
<i>Agnimandhya</i> (Anorexia)	Trial	70.82	3541.00	-7.856	234	< 0.0001 S
	Control	0.7667	0.4302			

Table 7 Overall Assessment criteria

Sr. No.	Assessment	Group A		Group B		Total	
		Count	%	Count	%	Count	%
01	Marked Improvement	48	96.00%	03	06.00%	51	51.00%
02	Moderate Improvement	02	04.00%	47	94.00%	49	49.00%
03	Mild Improvement	00	00.00%	00	00.00%	00	00.00%
04	Poor Improvement	00	00.00%	00	00.00%	00	00.00%
05	Unchanged	00	00.00%	00	00.00%	00	00.00%
	Total	50	100 %	50	100 %	100	100 %
	Chi Square Value		81.03	P value	<0.0001		

OBSERVATIONS

A majority of patients (82%) were reported in age greater than 40 years. The observed M: F ratio was 1.27:1. The diet wise distribution shows that the 60% patients are vegetarians. Most of the patients (63%) were doing job as consideration with occupation.

RESULTS

By statistical analysis, it was proved that, *Kasavega* (i.e., coughing), *Peenasa* (i.e. Running Nose), *Nisthivan Ghanakapham* (i.e. Productive Cough), *Shwaskashtata* (Dyspnea) and *Agnimandhya* (Anorexia) were improved in both groups (Table No.4 , Table No.5). Wilcoxon signed rank test was highly significant in subjective criteria of both the groups. That means both the drugs are effective in reducing symptoms of *Kaphaj Kasa* (Table No. 4). Mann Whitney U test was applied for subjective parameters to compare the efficacy of both the drugs, there was significant difference between efficacy of both the groups. It suggests that, there

is significant difference between the efficacy of both the drugs in *Kaphaj Kasa* (Chronic bronchitis). So, *Triphala Pippali Churna* was more effective in *Kaphaj kasa* than *Vasavaleha* (Table No. 6).

In overall assessment (Table No. 7), out of 100 patients 48 and 03 patients showed Marked Improvement in Group A and Group B respectively. So, Group A group drug is much more effective than group B drug. In group A 96% patients showed marked improvement compared to group B i.e., only 6 %. 2 and 47 patients were moderately improved in Group A and Group B respectively. No patients showed mild improvement, poor improvement in both the groups. It is clearly seen from table that group A drug is more effective than group B drug in *Kaphaj kasa* patients. The Chi-Square Statistic is 81.03. The p-value is less than 0.0001. There is significant difference in overall assessment in both the groups as p<0.05. Hence group A drug is

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more effective than group B drug as per overall assessment is concerned.

DISCUSSION

Triphala consists of *Haritaki*, *Amalaki* and *Bibhitaka* (Table No. 2)⁹. All the ingredients of *Triphala Pippali churna* are *tikta*, *katu*, *kashaya*, *ushna sheeta virya* acts as *deepana pachana kaphagna vatanuloma grahi* plays important role in the treatment of *kaphaj kasa*. They are given with *Anupana Madhu*. *Triphala* and *Pippali* is easily available in the market at very lost cost and having no side effects.

The conventional remedies available in the market are Bronchodilators used for a long period actually worsen the symptoms, overuse of bronchodilators causes trembling in hands, dry mouth, palpitations, muscle cramps, nausea, vomiting and sometimes diarrhea. So, it was decided to use ayurvedic drugs for the study.

Vasavaleha is classical herbal medicine available in the form of a jam or paste, which is mainly used in treating respiratory disorders. It offers respite from a host of respiratory ailments like asthma, bronchitis, and chronic cough. It is an incredible expectorant that is beneficial in alleviating respiratory problems by dissolving the sticky phlegm and expelling it. *Vasavaleha* is already established drug in *Kaphaj kasa*. So, selected drug for the Group B patients.

Mode of action of the Drug:

Triphala:

- *Triphala* is a combination of three fruits:

Amla (*Emblica officinalis*), *Haritaki* (*Terminalia chebula*), and *Bibhitaki* (*Terminalia bellirica*).

- *Amla* is rich in vitamin C and exhibits potent antioxidant properties. It helps in reducing inflammation and strengthening the immune system, which is beneficial in respiratory conditions.
- *Haritaki* has antimicrobial and expectorant properties. It helps to loosen mucus and facilitate its expulsion from the respiratory tract.
- *Bibhitaki* acts as a bronchodilator, helping to improve airflow in the lungs and alleviate symptoms such as wheezing and breathlessness.

Pippali (*Piper longum*):

- *Pippali*, also known as long pepper, is a potent bioenhancer and helps in the absorption and assimilation of nutrients. It improves the bioavailability of the active constituents of *Triphala*, enhancing its overall efficacy.
- *Pippali* has bronchodilator properties and helps to clear congestion in the respiratory passages. It also acts as an expectorant, facilitating the expulsion of phlegm

Synergistic Action:

- The combination of *Triphala* and *Pippali churna* creates a synergistic effect, where the individual properties of each component are enhanced when used together.
- *Triphala's* antioxidant and immunomodulating properties complement *pippali's* bronchodilator and expectorant actions, providing comprehensive support in managing *kaphaj kasa*.
- Together, they help to reduce inflammation,

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clear respiratory congestion, strengthen the immune system, and improve overall respiratory function.

Ayurvedic Perspective:

- According to *Ayurveda*, *kaphaj kasa* is characterized by an imbalance of the *kapha dosha*, leading to excess mucus production, congestion, and cough.
- *Triphala pippali churna* helps to pacify the aggravated *kapha dosha* by its drying, warming, and expectorant properties, thereby alleviating the symptoms associated with *kaphaj kasa*.
- Additionally, the combination of *Triphala* and *pippali churna* helps to restore balance to the body's overall constitution (*prakriti*), addressing the root cause of the respiratory imbalance.

Limitations of the study:

1. Sample Size and Generalizability:

- Limited sample size: The trial has a small sample size, which could affect the statistical power and generalizability of the findings.
- Homogeneity of sample: Participants are predominantly from a specific demographic or geographic region; it may limit the generalizability of the results to other populations.

2. Outcome Measures:

- Subjective outcome measures: Reliance on subjective measures, such as patient-reported symptoms or clinician assessments, may introduce variability and bias.

3. Confounding Variables:

- Uncontrolled confounders: Factors such as

concurrent medications, lifestyle habits, environmental exposures, or comorbidities that are not adequately accounted for in the study design may confound the observed treatment effect.

Scope of further study:

1. Dose Optimization:

- Investigate the optimal dosage and formulation of *Triphala pippali churna* for different subtypes of *kasa* and varying severity of chronic bronchitis.
- Conduct dose-ranging studies to determine the minimum effective dose and potential dose-response relationships.

2. Comparative Studies:

- Compare the efficacy and safety of *Triphala pippali churna* with conventional treatments for chronic bronchitis, such as bronchodilators, corticosteroids, and mucolytics.
- Evaluate the synergistic effects of *Triphala pippali churna* when used in combination with standard therapies versus monotherapy.

3. Mechanistic Studies:

- Elucidate the underlying mechanisms of action of *Triphala pippali churna* at the molecular and cellular levels, including its effects on inflammation, mucus production, immune modulation, and respiratory function.
- Explore the impact of *Triphala pippali churna* on specific biomarkers or pathways associated with *kaphaj kasa*, such as cytokine profiles, oxidative stress markers, and airway remodeling.

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4. Long-Term Outcomes:

- Conduct longitudinal studies to assess the long-term efficacy and safety of *Triphala pippali churna* in preventing disease progression, reducing exacerbations, and improving quality of life in patients with chronic bronchitis.
- Investigate the potential role of *Triphala pippali churna* as a maintenance therapy for preventing recurrence and maintaining remission in chronic respiratory conditions.

5. Adjuvant Therapies:

- Evaluate the efficacy of *Triphala pippali churna* in combination with other *Ayurvedic* formulations, lifestyle modifications, or integrative therapies for synergistic effects in managing *kaphaj kasa*.
- Investigate the potential role of *Triphala pippali churna* as an adjunctive therapy in multidisciplinary approaches for holistic respiratory care, including *yoga*, *pranayama*, and dietary interventions.

CONCLUSION

Thus, from above study it can be concluded that *Triphala Pippali Churna* is significantly effective in *Kaphaj kasa* (Chronic Bronchitis) as compared to *Vasavaleha*.

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