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A randomised controlled clinical study to evaluate the efficacy of *Oriladi Kashaya* (*Saliparnyadi Kashaya*) and *Vyaghradi Kashaya* in *Tamaka Shwasa w. s. r. to* Bronchial Asthma

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Abstract

Background

Tamaka Shwasa (Bronchial Asthma) is a severe *Vata-Kaphaja* respiratory disorder originating from *Amashaya* and manifesting in the *Pranavaha Srotas*, affecting over 35 million people in India and 300 million globally. In clinical practice, conservative *Shamana Chikitsa* (palliative therapy) is highly preferred for managing mild-to-moderate conditions in outpatient settings over radical *Shodhana* (purificatory procedures).

Aim

To evaluate and compare the clinical efficacy of the trial formulation *Oriladi Kashaya* (*Saliparnyadi Kashaya*) and the standard formulation *Vyaghradi Kashaya* in the management of *Tamaka Shwasa* (*w.s.r. to* Bronchial Asthma).

Materials and Methods

A single-blind, parallel-group randomised controlled clinical trial was conducted on 40 patients with mild-to-moderate *Tamaka Shwasa* selected from the Outpatient Department of Rajarajeshwari Ayurvedic Medical College and Hospital, Humnabad. Patients were randomly assigned via lottery method into two groups of 20 each. Group A received *Oriladi Kashaya* (1 *Pala* / 48 ml daily in divided doses [24 ml twice daily] with *Jala* as *Anupana*), while Group B received *Vyaghradi Kashaya* (1 *Pala* / 48 ml daily with *Jala*) for 21 days with follow-up on the 28th day. Subjective parameters (*Shwasa Krichrata*, *Urah Peeda*, *Kapha Nishteevana*, *Shwasa Vega*, *Ghurghuraka*, *Kasa*, *Peenasa*) and objective parameter (Peak Expiratory Flow Rate - *PEFR*) were evaluated before and after treatment.

Results

Both interventions demonstrated statistically significant improvement across all assessed parameters ($p < 0.001$).

However, inter-group comparison revealed that *Vyaghradi Kashaya* yielded statistically superior outcomes compared to *Oriladi Kashaya*, particularly in reducing *Kapha Nishteevana* (84.9% relief, p = 0.001) and improving *PEFR* (80.6% improvement, p = 0.012).

Conclusion

Although *Oriladi Kashaya* provides important *Rasayana-Balya* and tissue-supportive benefits, *Vyaghradi Kashaya* acts more potently on clearing *Kapha*-mediated airway obstruction and enhancing pulmonary airflow in *Tamaka Shwasa*.

Keywords

Tamaka Shwasa, Bronchial Asthma, *Oriladi Kashaya*, *Saliparnyadi Kashaya*, *Vyaghradi Kashaya*, *Shamana Chikitsa*, *Pranavaha Srotas*, Peak Expiratory Flow Rate (*PEFR*).

Introduction

Shwasa denotes both physiological and pathological respiration and is an essential function of the *Pranavaha Srotas.* In *Tamaka Shwasa*, the normal respiratory function is impaired, resulting in characteristic respiratory distress.

According to *Acharya Charaka*, aggravated *Vata* in the chest stimulates *Kapha*, causing obstruction in the *Pranavaha Srotas* and resulting in *Shwasa Roga*[1]. *Acharya Vagbhata* describes the involvement of *Prana, Udaka,* and *Annavaha Srotas*, with vitiated *Vata* and *Kapha* contributing to the manifestation of the disease[2].

Tamaka Shwasa is primarily a Vata-Kaphaja Vyadhi originating from *Amashaya* and involving the *Pranavaha Srotas*[3]. Its characteristic features include *Ghurghuraka* (wheezing), *Shwasa Vega, Kasa, Peenasa,*[4] .

The presentation of *Tamaka shwasa* is peculiar, it is *pittasthanasamudbhava*[5] *pranovaha srotovikara* in which *avarudhamarga* of *Pranvayu*[6] due to morbid kapha is principle pathology involved. Vitiated *doshas* afflicts *Rasadhatu* involves the *Pranavaha srotas* and produces the illness. In contemporary Science, it seems identical to Bronchial Asthma

Bronchial asthma is a chronic inflammatory airway disorder characterised by airway hyper-responsiveness, variable/reversible airflow obstruction, wheezing, cough, chest tightness, and dyspnoea.[7]

Both Ayurvedic and modern perspectives recognise the importance of endogenous and environmental factors in disease causation, highlighting *Nidana Parivarjana* as an important management principle.

Respiratory diseases constitute a major global health, social, and economic burden. According to the Global Asthma Report cited in the study, approximately 35 million people in India and 300 million worldwide were affected by asthma, with the global burden reported to have increased by 50% over the preceding decade[8]. Increasing air pollution, urbanization, dietary changes, overcrowding, and reduced immunity further contribute to the growing burden of respiratory disorders.

Hence, developing effective, safe, economical, and minimally adverse therapies, particularly for mild-to-moderate asthma, remains important. In *Ayurveda*, *Shamana* and *Brimhana Chikitsa* are emphasised appropriately over *Shodhana*,

with *Shamana Chikitsa* being suitable for mild-to-moderate disease and feasible in an outpatient setting.

The management of respiratory disorders is becoming a challenge to the medical world. Ayurveda the ancient system of medicine provides a lot of hope in assuring better results in the field of prevention and management of respiratory disorders.

While explaining the treatment of *Shwasa roga* , *Acharyas* have mentioned the importance of *Shamana* and *Brimhana chikitsa* over *shodhana chikitsa*. *Shamana chikitsa* is applicable for even in patients of mild and moderate strength and can also be done in OPD basis.

Considering all these aspects, the present study has been framed to evaluate the efficacy of two Ayurvedic formulations namely *Oriladi kashaya (Saliparnyadi Kashaya)*[9] mentioned in *Sahasrayogam* and *Vyaghradi Kashaya*[10] mentioned in *Ashtanga Hridayam Chikitsa sthana.*

Aims and Objects

Primary Objective

To evaluate and compare the clinical efficacy of the trial drug *Oriladi Kashaya* (*Saliparnyadi Kashaya*) and the standard control drug *Vyaghradi Kashaya* in patients suffering from *Tamaka Shwasa* (Bronchial Asthma).

Secondary Objectives

1. To evaluate the individual therapeutic efficacy of *Oriladi Kashaya* in relieving symptoms of *Tamaka Shwasa*.
2. To evaluate the individual therapeutic efficacy of *Vyaghradi Kashaya* in relieving symptoms of *Tamaka Shwasa*.

Materials and Methods

Source of Data

Literary Source

Relevant classical *Ayurvedic* texts, modern medical literature, peer-reviewed journals, and authentic electronic databases were thoroughly reviewed to compile comprehensive theoretical data regarding *Tamaka Shwasa* and the trial formulations.

Pharmaceutical Source

The formulations selected for this study—*Oriladi Kashaya* and *Vyaghradi Kashaya*—were freshly prepared at the Pharmacy of Rajarajeshwari Ayurvedic Medical College, Humnabad, adhering strictly to classical pharmaceutical guidelines. Authentic raw plant drugs were identified, verified, and procured locally and from certified *Ayurvedic* vendors.

Clinical Source

Patients exhibiting mild and moderate signs and symptoms of *Tamaka Shwasa* (Bronchial Asthma) were recruited from:

- The Outpatient Department (OPD) of Post Graduate Studies in *Kayachikitsa*, Rajarajeshwari Ayurvedic Medical College and Hospital, Humnabad, Bidar District, Karnataka.
- Peripheral medical camps and clinical referral networks.

Method of Collection of Data

Sample Size and Group Allocation

A minimum sample size of 40 patients fulfilling the inclusion criteria, irrespective of gender, religion, or socio-economic status, was enrolled. Patients were

randomly assigned into two equal groups of 20 patients each:

- **Group A (Trial Group)**: 20 patients
- **Group B (Standard Group)**: 20 patients

Study Design, Blinding, and Sampling Method

- **Study Design**: Parallel-group comparative clinical trial.
- **Blinding**: Single-blind design.
- **Sampling Method**: Simple random sampling via Lottery Method.

Plan of Study (Treatment Protocol)

Interventional Parameter	Group A (Trial Group)	Group B (Standard Control Group)
Formulation	*Oriladi Kashaya* (*Saliparnyadi Kashaya*)	*Vyaghradi Kashaya*
Posology / Dose	1 *Pala* (48 ml/day in divided doses: 24 ml twice daily)	1 *Pala* (48 ml/day in divided doses: 24 ml twice daily)
Vehicle (*Anupana*)	*Jala* (Warm Water)	*Jala* (Warm Water)
Administration Time	Before meals (Twice daily: Morning & Evening)	Before meals (Twice daily: Morning & Evening)
Treatment Duration	21 consecutive days	21 consecutive days
Follow-Up Assessment	28th day (7 days post-treatment)	28th day (7 days post-treatment)
Total Study Period	30 days (including follow-up)	30 days (including follow-up)

Observation Schedule

Patients were clinically reassessed at regular intervals on Day 7, Day 14, and Day 21 during treatment, with a post-treatment follow-up evaluation on Day 28.

Diagnostic Criteria

Diagnostic confirmation was established based on clinical features of *Tamaka Shwasa* and international guidelines:

- *Shwasa Krichrata* (Difficulty in breathing / dyspnea).
- *Urah Peeda* (Chest tightness / pain).
- Expectoration of sputum (*Kapha Nishteevana*), present with or without paroxysms.
- *Ghurghuraka* (Audible wheezing on chest auscultation).
- *Kasa* (Cough).
- *Peenasa* (Coryza / rhinitis).
- Peak Expiratory Flow Rate (*PEFR*) between 80 L/min and 300 L/min.
- Diagnostic criteria established by the Global Initiative for Asthma (GINA).

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Patients aged between 16 and 60 years fulfilling the diagnostic criteria.

2. Patients presenting with mild to moderate clinical symptoms of *Tamaka Shwasa*.
3. Newly diagnosed (fresh) cases of Bronchial Asthma.
4. Previously diagnosed cases of Bronchial Asthma who were not on active medication at the time of recruitment.
5. Patients willing to give informed consent and comply with trial procedures.

Exclusion Criteria

1. Patients aged below 16 years or above 60 years.
2. Patients suffering from severe systemic co-morbidities (cardiac, renal, or hepatic disorders).
3. Patients diagnosed with lung carcinoma or structural pulmonary pathologies.
4. Patients presenting with acute severe asthmatic paroxysms requiring immediate nebulization, oxygen therapy, or emergency intensive care.
5. Patients with complicated respiratory conditions such as Pulmonary Tuberculosis, Pneumonia, Chronic Obstructive Pulmonary Disease (COPD), or bronchiectasis.
6. Patients currently on systemic corticosteroid therapy.
7. Pregnant and lactating women.
8. Patients with a chronic history of tobacco smoking or substance addiction.

Assessment Criteria

Subjective Parameters

Grading of clinical severity (mild and moderate) was conducted using a standardized semi-quantitative scoring performa based on classical *Lakshana* of *Tamaka Shwasa*:

1. *Shwasa Krichrata* (Dyspnea grade)
2. *Shwasa Vega* (Paroxysms of dyspnea)
3. *Ghurghuraka* (Wheezing sound)
4. *Urah Peeda* (Chest tightness)
5. *Kasa* (Severity of cough)
6. *Peenasa* (Nasal congestion/rhinitis)
7. *Kapha Nishteevana* (Ease and quantity of sputum expectoration)

Objective Parameter

Peak Expiratory Flow Rate (*PEFR*) measured in liters per minute using a calibrated Wright Peak Flow Meter before intervention, during treatment, and at follow-up.

Laboratory Investigations

Routine hematological assessments (Complete Blood Count, Erythrocyte Sedimentation Rate) and Chest X-Ray (Posterior-Anterior and Lateral views) were conducted wherever clinically indicated to exclude non-eligible pathologies.

Observations

Demographic and clinical baseline observations were recorded across the 40 enrolled patients. Patients maintained compliance throughout the 21-day

therapeutic window and the subsequent 7-day follow-up period. Periodic clinical scoring on Days 7, 14, 21, and 28 demonstrated progressive symptomatic relief in both treatment arms.

Results

Statistical analysis was conducted to assess intra-group efficacy using the Wilcoxon Signed-Rank Test and inter-group comparative efficacy using the Mann-Whitney U Test.

Intra-Group Therapeutic Efficacy

Effect of *Vyaghradi Kashaya* (Group B)

Group B (*Vyaghradi Kashaya*) demonstrated statistically significant reductions in symptom severity and marked improvement in objective airflow measurements ($p < 0.001$ across all parameters).

Table 1: Intra-Group Effect of *Vyaghradi Kashaya* on Subjective and Objective Parameters (Group B, N = 20)

Clinical Parameter	Mean BT	Mean AT	Median	Standard Deviation (SD)	Standard Error (SE)	Wilcoxon W Test	p-Value	Relief / Improvement (%)
Kasa (Cough)	2.50	0.70	1.00	0.489	0.109	-3.976	< 0.001	72.0%
Shwasa Krichrata (Dyspnea)	2.35	0.70	1.00	0.489	0.109	-4.072	< 0.001	70.2%
Ghurghuraka (Wheezing)	2.45	0.65	1.00	0.489	0.109	-3.982	< 0.001	73.5%
Urah Peeda (Chest Tightness)	2.65	0.71	1.00	0.489	0.109	-3.974	< 0.001	73.2%
Peenasa (Rhinitis)	1.90	0.70	1.00	0.470	0.105	-4.021	< 0.001	63.2%
Shwasa Vega (Asthmatic Attacks)	2.65	0.75	1.00	0.470	0.105	-4.008	< 0.001	71.7%
Kapha Nishteevana (Expectoration)	2.65	0.40	0.00	0.489	0.109	-4.035	< 0.001	84.9%
PEFR (Peak Flow Rate)	1.80	0.35	0.00	0.489	0.109	-3.874	< 0.001	80.6%

Inter-Group Comparative Analysis

Comparative evaluation using the Mann-Whitney U Test revealed that while both formulations produced significant clinical recovery, *Vyaghradi Kashaya* achieved statistically superior therapeutic relief compared to *Oriladi Kashaya* across all parameters.

Table 2: Comparative Inter-Group Analysis between Group A (*Oriladi Kashaya*) and Group B (*Vyaghradi Kashaya*)

Parameter	Study Group	Sample (N)	Mean Rank	Sum of Ranks	Mann-Whitney U	p-Value	Statistical Inference
Shwasa Krichrata	Group A (*Oriladi*)	20	23.50	470.00	140.50	0.019	Statistically Significant ($p < 0.05$)
	Group B (*Vyaghradi*)	20	17.50	350.00			
Urah Peeda	Group A (*Oriladi*)	20	23.50	470.00	140.00	0.019	Statistically Significant ($p < 0.05$)
	Group B (*Vyaghradi*)	20	17.50	350.00			
Kapha Nishteevana	Group A (*Oriladi*)	20	26.50	530.00	80.00	0.001	Statistically Highly Significant ($p < 0.01$)
	Group B (*Vyaghradi*)	20	14.50	290.00			
Shwasa Vega	Group A (*Oriladi*)	20	23.00	460.00	150.00	0.040	Statistically Significant ($p < 0.05$)
	Group B (*Vyaghradi*)	20	18.00	360.00			
Ghurghuraka	Group A (*Oriladi*)	20	23.50	470.00	140.00	0.027	Statistically Significant ($p < 0.05$)
	Group B (*Vyaghradi*)	20	17.50	350.00			
Kasa	Group A (*Oriladi*)	20	23.00	460.00	150.00	0.042	Statistically Significant ($p < 0.05$)

	Group B (*Vyaghradi*)	20	18.00	360.00			
Peenasa	Group A (*Oriladi*)	20	23.00	460.00	150.00	0.040	Statistically Significant ($p < 0.05$)
	Group B (*Vyaghradi*)	20	18.00	360.00			
PEFR	Group A (*Oriladi*)	20	24.50	490.00	120.00	0.012	Statistically Significant ($p < 0.05$)
	Group B (*Vyaghradi*)	20	16.50	330.00			

Discussion

The pathogenesis of *Tamaka Shwasa* revolves around the vitiation of *Vata* and *Kapha Doshas*, leading to *Ama* formation, *Agni* impairment, and subsequent *Srotorodha* (channel obstruction) in the *Pranavaha Srotas*. Pharmacological interventions must therefore possess properties that break this pathogenesis (*Samprapti Vighatana*) through *Deepana-Pachana* (digestive-carminative), *Kapha-Vatahara*, and *Srotoshodhaka* (channel-clearing) mechanisms.

Pharmacodynamics of *Oriladi Kashaya* (*Saliparnyadi Kashaya*)

Oriladi Kashaya is composed of *Shaliparni* (*Desmodium gangeticum*), *Prishniparni* (*Uraria picta*), *Brihati* (*Solanum indicum*), *Shatavari* (*Asparagus racemosus*), *Kasamarda* (*Senna occidentalis*), *Ardraka* (*Zingiber officinale*), *Jivanti* (*Leptadenia reticulata*), and *Vasa* (*Adhatoda vasica*).

- **Properties**: Possesses predominantly *Vata-Kaphahara*, *Shwasahara*, *Kasahara*, *Deepana*, *Pachana*, *Rasayana*, and *Balya* pharmacological profiles.
- **Mode of Action**: Facilitates *Kapha Vilayana* (liquefaction of mucus), alleviates *Pranavaha Srotorodha*, normalizes the physiological movement of *Vata* (*Anulomana*), and mitigates bronchial mucosal inflammation. Additionally, its inherent *Rasayana* and *Balya* attributes impart strength to the lung parenchyma and respiratory musculature, reducing bronchial hyper-responsiveness over long-term management.

Pharmacodynamics of *Vyaghradi Kashaya*

Vyaghradi Kashaya comprises *Vyaghri* / *Kantakari* (*Solanum xanthocarpum*), *Shunthi* (*Zingiber officinale*), *Guduchi* (*Tinospora cordifolia*), and *Pippali* (*Piper longum*).

- **Properties**: Primarily exhibits *Ushna Virya*, *Katu Vipaka*, *Deepana-Pachana*, *Kapha-Vatahara*, and potent *Srotoshodhaka* actions.

- **Mode of Action**: The therapeutic effect is mediated via intense *Ama Pachana* (digestion of toxic metabolic waste), rapid liquefaction and clearance of viscous *Kapha* from the bronchial tree, relief of bronchospasm, and opening of the obstructed airways. By directly targeting the acute obstructive component of *Tamaka Shwasa*, *Vyaghradi Kashaya* rapidly restores airway patency and ventilatory mechanics.

Comparative Therapeutic Synthesis

Both trial formulations achieved statistically significant improvement across all primary clinical endpoints ($p < 0.001$). However, inter-group analysis established the clear superiority of *Vyaghradi Kashaya* over *Oriladi Kashaya*, most markedly in clearing sputum expectoration (*Kapha Nishteevana*: 84.9% vs Group A, $p = 0.001$) and improving ventilatory capacity (*PEFR*: 80.6% vs Group A, $p = 0.012$). This distinction is attributed to the aggressive *Deepana-Pachana*, *Ushna*, and *Srotoshodhaka* properties of *Vyaghradi Kashaya*, which directly liquefy and expel tenacious *Kapha* plugs causing mechanical airway resistance. Conversely, *Oriladi Kashaya* offers a broader, tissue-tonifying (*Balya-Rasayana*) and anti-inflammatory profile suited for sustained maintenance therapy.

Conclusion

The clinical study confirms that both *Oriladi Kashaya* (*Saliparnyadi Kashaya*) and *Vyaghradi Kashaya* are effective, safe, and well-tolerated *Ayurvedic* formulations for managing mild-to-moderate *Tamaka Shwasa* (Bronchial Asthma) in an outpatient setting.

- **Key Finding**: *Vyaghradi Kashaya* demonstrates statistically superior therapeutic efficacy compared to *Oriladi Kashaya*, particularly in relieving *Kapha*-mediated airway obstruction (*Kapha Nishteevana*, 84.9% relief) and restoring peak expiratory airflow rates (*PEFR*, 80.6% improvement).
- **Clinical Recommendation**: *Vyaghradi Kashaya* is highly recommended as a first-line *Shamana* formulation for acute symptom control and channel clearing in *Tamaka Shwasa*, whereas *Oriladi Kashaya* serves as an effective long-term supportive therapy due to its *Rasayana* and *Balya* properties.

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