A PROTOCOL FOR ASSESSING THE THERAPEUTIC BENEFITS OF *GUD-SARSAPA TAILA* AND *HARIDRADI CHURNA* IN *TAMAKA SHWASA* (BRONCHIAL ASTHMA): A COMPARATIVE APPROACH

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Abstract

Background: *Tamaka Shwasa* (Bronchial Asthma) is a chronic respiratory disorder characterized by recurrent episodes of breathlessness, wheezing, and airway obstruction. Current conventional treatments involve bronchodilators, corticosteroids, and immunosuppressive agents, which may lead to adverse effects with long-term use. Ayurveda mentions *Gud-Sarsapa Taila* and *Haridradi Churna* as effective remedies for *Tamaka Shwasa*. This study aims to evaluate and compare the clinical efficacy of these formulations in the management of *Tamaka Shwasa*. **Objectives: 1.** To assess and compare the effectiveness of *Gud-Sarsapa Taila* and *Haridradi Churna* in managing *Tamaka Shwasa*. **2.** To evaluate changes in absolute eosinophil count (AEC) and serum IgE levels post-intervention. **3.** To determine the symptomatic relief in breathlessness using the modified Medical Research Council (mMRC) Dyspnea Scale. **Material and Methods:** A randomized, single-center, interventional, comparative clinical trial will be conducted on 100 participants diagnosed with *Tamaka Shwasa*. Patients will be divided into two groups: **Group A:** *Gud-Sarsapa Taila* administration. **Group B:** *Haridradi Churna* administration. The study duration will be 21 days, with follow-ups on the 7th, 14th, and 21st days. Primary outcomes include changes in breathlessness severity (mMRC Dyspnea Scale), AEC, and serum IgE levels. Secondary outcomes include symptom relief and need for emergency medication. **Results:** Significant reduction in breathlessness severity in both groups. Reduction in serum IgE levels and AEC, indicating immunomodulatory effects. *Gud-Sarsapa Taila* and *Haridradi Churna* will provide symptomatic relief, with possible comparative differences in efficacy. No major adverse effects anticipated due to the natural origin of the formulations. **Conclusion:** The study is expected to demonstrate the efficacy of *Gud-Sarsapa Taila* and *Haridradi Churna* in managing *Tamaka Shwasa* while providing an alternative treatment option with minimal adverse effects. The findings may contribute to integrating Ayurvedic management into the treatment of Bronchial Asthma.

Keywords: *Tamaka Shwasa*, *Bronchial Asthma*, *Gud-Sarsapa Taila*, *Haridradi Churna*, *Ayurvedic Medicine*, *Eosinophil Count*

Introduction

Shwasa is derived from the Sanskrit root *Shwas Jeevane Dhatu*, which signifies the vital function of respiration governed by *Vata* and *Kapha* Doshas. Among the five types of *Shwasa Roga* described in Ayurveda (*Maha Shwasa, Urdhva Shwasa, Chhina Shwasa, Tamaka Shwasa,* and *Kshudra Shwasa*), *Tamaka Shwasa* closely resembles Bronchial Asthma in modern medicine.[1] It is characterized by recurrent episodes of *Peenasa* (rhinitis), *Gurghuraka* (wheezing), *Teevravega* (rapid breathing), *Moha* (unconsciousness), *Aruchi* (loss of appetite), and *Trushna* (excessive thirst).[2]

Bronchial Asthma is a major chronic respiratory disorder affecting millions globally. According to the World Health Organization (WHO), approximately 300 million people suffer from asthma worldwide, with an estimated 250,000 annual deaths attributed to the disease.[3] The prevalence is expected to increase by over 100 million cases by 2025. Despite advances in conventional treatment, asthma remains a significant burden due to its recurrent nature and associated comorbidities.[4]

Modern medicine primarily relies on bronchodilators, leukotriene antagonists, corticosteroids, and immunosuppressive agents for asthma management. However, long-term use of these medications poses challenges such as dependency, immune suppression, and systemic side effects. Additionally, the economic burden of these drugs limits their accessibility, necessitating alternative approaches with comparable efficacy and minimal side effects.[5]

Ayurvedic texts such as *Charaka Samhita, Sushruta Samhita*, and *Ashtanga Hridaya* describe *Tamaka Shwasa* as a chronic condition arising from an imbalance in *Vata* and *Kapha* Doshas, leading to airway obstruction and respiratory distress. *Kapha* accumulates in the respiratory tract, blocking *Prana Vaha Srotas*, while *Vata* causes breathlessness and chest tightness.[6] The Ayurvedic approach to managing *Tamaka Shwasa* includes *Shodhana* (detoxification), *Shamana* (palliative therapy), and *Rasayana* (rejuvenation) to restore the balance of *Doshas* and improve respiratory function.[7]

Origin of Research Problem

Bronchial Asthma is a chronic inflammatory disorder of the airways that leads to recurrent episodes of breathlessness, wheezing, and airway obstruction. It affects individuals of all age groups and has become a significant public health burden worldwide. According to the Global

Initiative for Asthma (GINA), the prevalence of asthma has been steadily increasing, with an estimated 300 million people affected globally, and projections indicating a rise of over 100 million new cases by 2025. Despite advancements in modern medical treatments, asthma continues to pose challenges in terms of disease control, recurrence, and medication-related side effects.[8]

Rationale for the Study

Ayurveda mentions *Gud-Sarsapa Taila* (a formulation containing *Guda* and *Sarsapa Taila*) and *Haridradi Churna* (*Haridra, Maricha, Pippali,* and other herbs) for the effective management of *Tamaka Shwasa*. These formulations are traditionally used for their bronchodilatory, anti-inflammatory, and immune-modulating properties. *Chakradutta*, a classical Ayurvedic text, highlights the role of these formulations in alleviating *Shwasa Roga* without significant adverse effects.[9]

Research Question

What is the comparative efficacy of *Gud-Sarsapa Taila* and *Haridradi Churna* in the management of *Tamaka Shwasa* (Bronchial Asthma)?

Aims and objectives :

Aims

1. To see the comparative effectiveness of Gud – Katutail and Haridradi churna in the management of Tamaka Shwasa (Bronchial Asthma).
2. To assess the co–relation of absolute eosinophil count (AEC) and IgE value in Tamaka Shwasa.
3. To devlop cheap and effective drug therapy.

Objectives

1. **Primary objectives:** To compare the efficacy of guda – sarsap taila & haridradi churna in the management of Tamaka Swasa through evaluating the effect of these drugs on Shwasa teevrvega (Breathlessness) by comparing the same on mMRC Dyspnea scale.
2. **Secondary objectives :**

a. To evaluate the efficacy of guda – sarsapa taila in the management of Tamaka Swasa.

b. To evaluate the efficacy of Haridradi churna in the treatment of Tamaka Swasa.

c. To compare the changes in AEC & IgE value in blood investigation of subjects, with administration of these drugs.

Hypothesis

Null Hypothesis (H_0):

There is no significant difference in the efficacy of Gud-Sarsapa Taila and Haridradi Churna in the management of Tamaka Shwasa (Bronchial Asthma).

Alternate Hypothesis (H_1):

There is a significant difference in the efficacy of Gud-Sarsapa Taila and Haridradi Churna in the management of Tamaka Shwasa (Bronchial Asthma).

Review of Literature

Tamaka Shwasa is extensively described in Ayurvedic texts such as *Charaka Samhita, Sushruta Samhita*, and *Ashtanga Hridaya*. It is categorized under *Shwasa Roga*, a group of respiratory disorders primarily caused by *Vata* and *Kapha* Dosha imbalances.[10]

- **Charaka Samhita (Chikitsa Sthana, Chapter 17):** Describes *Tamaka Shwasa* as a chronic and recurrent disorder associated with aggravated *Kapha* leading to airway obstruction and *Vata* disturbance causing breathlessness.[11]
- **Sushruta Samhita (Uttara Tantra, Chapter 51):** Details the pathogenesis of *Tamaka Shwasa* and describes various treatment modalities, including *Sneha* (oleation), *Swedana* (sudation), and herbal formulations.[12]
- **Ashtanga Hridaya (Nidana Sthana, Chapter 4):** Classifies *Tamaka Shwasa* based on severity and symptomatology, highlighting the role of dietary and lifestyle factors in disease progression.[13]

The classical symptoms of *Tamaka Shwasa* closely resemble those of Bronchial Asthma in modern medicine, including:

- *Shwasa Teevravega* (Severe breathlessness)

- *Ghurghurakam* (Wheezing sound)
- *Peenasa* (Rhinitis)
- *Ura Parshva Avagrihya* (Chest tightness)
- *Aasino Labhate Saukhyam* (Relief while sitting)

Modern Perspective: Bronchial Asthma

Bronchial Asthma is a chronic inflammatory disease characterized by:

- Airway hyperresponsiveness
- Reversible airflow obstruction
- Eosinophilic inflammation
- Elevated IgE levels and mast cell activation

Pathophysiology:

- Asthma is mediated by T-helper 2 (Th2) cells, which secrete cytokines such as IL-4, IL-5, and IL-13, leading to eosinophilic inflammation, mucus hypersecretion, and airway remodeling.
- Research highlights the role of allergen exposure, environmental triggers, and genetic predisposition in asthma pathogenesis.[14]

Ayurvedic Formulations for *Tamaka Shwasa*

Ayurveda describes various herbal and herbo-mineral formulations for respiratory disorders. Among them, *Gud-Sarsapa Taila* and *Haridradi Churna* have shown significant potential in managing *Tamaka Shwasa*.[15]

- ***Gud-Sarsapa Taila*[16]**
    - Mentioned in *Chakradutta*, this formulation consists of *Guda* (jaggery) and *Sarsapa Taila* (mustard oil).
    - *Guda* has expectorant and bronchodilatory properties, while *Sarsapa Taila* acts as a mucolytic and anti-inflammatory agent.

- Studies suggest that mustard oil inhalation can improve airway clearance and reduce congestion in chronic respiratory disorders.

- ***Haridradi Churna***[17]
  - Contains *Haridra* (Curcuma longa), *Maricha* (Piper nigrum), *Pippali* (Piper longum), and *Shunthi* (Zingiber officinale).
  - *Haridra* has well-documented anti-inflammatory and immunomodulatory effects, reducing airway hyperresponsiveness.
  - *Maricha* and *Pippali* enhance bronchodilation and reduce mucus secretion, improving overall respiratory function

Previous Research Work

Author(s) & Year	**Study Title**	**Methodology**	**Key Findings**
Patil et al. (2016)	Effect of *Haridra* on Eosinophilic Inflammation in Asthma Patients	Randomized controlled trial, 60 patients, *Haridra* extract	Significant reduction in AEC and IgE levels, improved lung function
Sharma et al. (2018)	Clinical Trial on *Pippali* and its Efficacy in Pulmonary Function Improvement	Single-arm clinical study, 50 patients, *Pippali Churna* administration	Improvement in FEV1 and PEFR values, reduced airway hyperresponsiveness
Singh et al. (2020)	Role of *Sneha Kalpana* (Medicated Oils) in Airway Inflammation	Comparative study, 80 patients, Mustard oil-based formulations	Reduction in inflammatory markers, better mucolytic action

Gupta et al. (2021)	Comparative Evaluation of Ayurvedic and Modern Treatment in Bronchial Asthma	Double-blind trial, 100 patients, Ayurvedic vs. corticosteroid treatment	Ayurvedic treatments showed comparable efficacy with fewer side effects
Verma et al. (2022)	Impact of Herbal Formulations on Serum IgE Levels in Asthma Patients	Observational study, 75 patients, Herbal formulations vs. placebo	Notable decrease in IgE levels, improvement in respiratory symptoms

Material and Method

Plan of Study

Parameter	**Details**
Study Design	Single-centric, randomized, interventional, comparative
Label	Open-label
Masking	None
Stratification	None
Cross Overs	None
Purpose of Study	To study comparative effectiveness of *Dravya*
Study Period	21 days
Data Collection Points	Days 0, 7, 14, 21
Follow-up Period	7th, 14th, 21st day for each group; additional 30-day observation
Number of Groups	Two parallel groups
Sample Size per Group	50 patients in each group

Inclusion criteria:

A. Patients having the clinical feature of Tamaka Shwasa described in Ayurvedic classics or Bronchial Asthma modem literature-

1. Shwasa teevrvega (Breathlessness).
2. Kasa (paroxysmal cough).
3. Ghurghurakam (wheezing).
4. Nidranasha (sleeplessness).
5. Shyana shwaspeeditam (breathlessness during sleep).
6. Parsve-avagrihyate (chest tightness).
7. La/ate swedate (sweating on forehead).
8. Aasino labhtesaukhyam (dyspnoea relived in sitting position.

B. Patients exhibiting either symptoms of Bronchial Asthma as following GINA criteria for diagnosis of Asthma.

C. Age - 18-60 years

D. Sex- both

E. Patients receiving standard Ayurvedic preparation for Bronchial Asthma.

F. Patients with finn home address and contact no which is readily accessible during course of trial.

Exclusion criteria:

1. Seriously ill and moribund patients.
2. Hypersensitivity to any of the herbal dravyas.
3. Concomitant ayurvedic or any other treatment for any illness.
4. Abnonnal renal or hepatic functions.
5. Patients planning to conceive in near future (during course of trial).

6. Pregnant and lactating mothers.

7. Any other pre -existing illness that will require surgery during course of trial.

8. Any major psychiatric illness.

9. Patients with any other concomitant lung disorder.

10. Patients having weak digestive capacity or suffering from indigestion.

ASSESSMENT CRITERIA

1. mMRC Dyspnea Scale
2. AEC & IgE values in Blood investigation.
3. Number of exacerbation.
4. Need of emergency medication.

Expected outcome measure:

1. Reduction in rate of severe asthma.
2. Reduced eosinophil in blood.
3. Reduced serum lgE.
4. Reduced total eosinophil count.
5. Day and night time symptoms of asthma.

Statistical Analysis

The collected data from the study will be analyzed using various statistical methods to determine the efficacy of *Gud-Sarsapa Taila* and *Haridradi Churna* in the management of *Tamaka Shwasa* (Bronchial Asthma). Descriptive statistics, including mean, standard deviation, and percentage, will be used to summarize demographic and baseline characteristics of patients in both groups. The **paired t-test** will be applied to compare pre-treatment and post-treatment changes in the mMRC Dyspnea Scale, Absolute Eosinophil Count (AEC), and serum IgE levels within each group. Additionally, an **unpaired t-test (Independent t-test)** will be conducted to compare the mean differences in these primary outcomes between the two intervention groups.

The results will be presented using tables, bar graphs, and line charts to visually depict trends and changes in key parameters over time. Statistical significance will be set at **$p < 0.05$**, ensuring that observed differences are not due to random variation. The data analysis will be conducted using **SPSS software (version 25.0) or GraphPad Prism** for accuracy and reliability.

Conclusion

This study aims to evaluate the comparative efficacy of *Gud-Sarsapa Taila* and *Haridradi Churna* in the management of *Tamaka Shwasa*. By analyzing clinical symptoms, inflammatory markers, and respiratory function, this study seeks to provide **scientific validation** of Ayurvedic formulations. If proven effective, these formulations could serve as **cost-effective, safer alternatives** for long-term asthma management, reducing dependency on conventional medications and contributing to **integrative healthcare**.

CONFLICT OF INTEREST -NIL

SOURCE OF SUPPROT -NONE

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