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A Comparative Study to Evaluate the Effectiveness of *Abhaya-Nagara Churna* and *Vasavaleha* in management of *Tamaka Swasa* ~ Bronchial Asthma: Protocol

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ABSTRACT

Background: *Tamaka swasa*, is a clinical condition characterised by *swasakruchrta* (dyspnoea), due to obstruction of *pranvaha srotas* by vitiation of *Kapha* and *Vata doshas* leading to *partiloma gati* (inverse movement) of *Vata*. It has manifestations similar to Bronchial Asthma, a disorder of airways hyperresponsiveness resulting in wheeze, breathlessness, chest tightness and coughing. According to the Indian Study on Epidemiology of Asthma, Respiratory Symptoms, and Chronic Bronchitis (INSEARCH), the asthma prevalence across India is approximately 2.05 per cent among those aged more than 15 years.

Aim: This study aims to evaluate and compare the effectiveness of *Abhaya-Nagara Churna* and *Vasavleha* in *Tamaka Swasa*.

Materials and Methods: This will be a single-centred, open-label, randomized clinical trial. The patients diagnosed with asthma will be selected and randomly divided into 2 groups. *Vasavleha* will be allocated to group A and *Abhaya-Sunthi Churna* to group B for 28 days. Haematological examination, spirometry and ACT score with a recall period of four weeks will be assessed before treatment and after treatment, while assessment of severity criteria will be done on 1st, 7th, 14th and 28th day. AQLQ score with recall period of two week will be assessed at the 1st, 14th and 28th days. Follow-up of 30 days will be done. The effect of the therapy will be evaluated based on the changes in subjective and objective parameters with a 'p' value < 0.05 as significant.

Discussion and Conclusion: The discussion and conclusion will be drawn on the basis of statistical analysis and symptomatic relief of overall assessment.

Key Words *Tamaka Swasa*, *Abhaya-Nagara churna*, *Asthma Control Test Score*, *Vasavleha*, *Asthma Quality of Life Questionnaire*

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INTRODUCTION

Tamaka swasa is a clinical condition characterised by *swasakrichra* (dyspnoea). It is a *yapya* type of *Swasa* (dyspnoea) mentioned in *Ayurveda* literature caused by obstruction of *pranvaha srotas* by vitiation of *Kapha* and *Vata*

doshas leading to *partiloma gati* (inverse movement) of *Vata*, which results in *Shwasa krucchrata* (dysnoea)¹.

Primary etiological factors for *Tamaka Swasa* are exposure to the *raja* (dust), *dhuma* (smoke), *sheeta sthan ambu sevan* (cold), *vyayam*

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(exercise), *gramyadharmā* (sexual activities), *ruksha anna* (dry food), *vishamashan* (irregular diet), *raukshya*, *apatarapana* (fasting), *aama dosha*¹.

Nidana arthakara roga (secondary etiological factors) of *swasa roga* are *atisara*, *jwara*, *chhardi*, *pratishaya*, *khsata*, *khasya*, *raktapitta*, *udaravatta*, *vichuchika* and *alāsaka*¹.

Aggravating factors for *tāmaka swasa* are *megha* (cloudy/rainy day), *sheeta* (cold), *pragaVata* (eastern wind), *sheleshma vardhaka ahara* (a diet that vitiates *Kapha dosha*)¹.

It is *pittasthana samudbhava vyadhi* (site of origin is the upper part of G.I.T) characterised by *Swasa vega* (asthmatic episode), *Swasakricchrata* (dyspnoea), *Ghurghuruka* (wheeze), *Kasa* (cough), *Krichrabhasana* (dysphasia), *Anidra* (disturbed sleep)¹.

Tāmaka Swasa has similar manifestations as **Bronchial Asthma**, an episodic, chronic inflammatory disorder with airway hyper-responsiveness causing recurrent episodes of breathlessness, wheezing, chest tightness and coughing, particularly at night and in the early morning².

According to W.H.O., approximately 300 million people around the world are suffering from Bronchial Asthma, which is expected to add up 100 million more by the end of the year 2025³. The Indian Study on Epidemiology of Asthma, Respiratory Symptoms, and Chronic Bronchitis (INSEARCH), included 84,470 women and 85,105 men from 12 urban and 11 rural sites across India, the prevalence rate of asthma was

estimated to be 2.05 per cent among those aged >15 years⁴.

Modern science has various drugs for the treatment of Bronchial Asthma however, long-term and regular use of these treatments may lead to side effects, such as dysphonia, mood changes, osteoporosis and hoarseness of voice⁵.

Both *haritaki* and *shunthi* are widely practised medicine in Ayurveda, with easy availability in every kitchen and are safely used in every age group from paediatric to geriatric patients. Theoretically, it seems an ideal drug for the management of *Tāmaka swasa*. There have been various studies conducted on *Tāmaka Swasa*, but study on effectiveness of *Abhaya-Nagara churna* in adults and comparative study with *Vasavleha* has not been conducted.

Abhaya-Nagara churna consists of *Haritaki* and *Shunthi* in the ratio of (3:1), with *ushnaodaka* as anupana⁶. *Haritaki* is *Kashaya pradhana pancharasa*, *ushna* and *tridosha shamaka*. It has *kanthya* and *swarya* effect on *pranvaha srotas* and is specifically mentioned in *swara vicar*, *swasa*, *kasa* and *rajyakshama*⁷. According to *Charaka*, *Haritaki* is *Doshaanulomni* and it's also *Vata hara*; thus, it may lead to *anulomana* of *Vata*. It is also mentioned that it swiftly abolishes *srotovibandha* and *pralepa* (~Congestion) of *hridaya* and *urha Pradesh* (thoracic region)⁸. Thus, it can nullify the *Kaphavibandha*, which causes *pratiloma gati* of *Vata*, which are essential pathognomonic characteristics of *swasa*.

Shunthi, is *katu rasa*, *Madhura vipaka*, *ushna virya* and *Vata-Kapha ghana*. It has *laghu*,
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*snigdha and Vata anulomana karma*⁹. Thus, it is also an ideal drug to nullify the *samprapti* of *swasa* by causing *Vata-Kapha shamana* and *anulomana* of the *pratiloma Vata*.

Vasa avaleha is mentioned in *Bhaishajya Ratnavali Kasa Roga Chikitsa*¹⁰. *Vasa* (*Adhatoda vasica*) is *Tikta rasa*, *Ruksha*, *Sheeta virya*, *Katu vipaka* and *Deepana*, *Anuloman*¹¹. *Pippali* (*Piper Longum*) is *Katu rasa*, *Ruksha*, *anushnasheeta*, *Madhura vipaka* and *Deepana*, *Anulomaka*¹². *Sita* is *Madhura rasa*, *Snigdha*, *Sheeta virya*, *Madhura vipaka* and *Vatahara*, *Dhatuvridhakara*¹³. *GoGhrita* is *Madhura rasa*, *Snigdha*, *Guru*, *Sheeta virya*, *Madhura vipaka* and *Tridosahara*¹⁴. *Madhu* is *Kashaya-Madhura rasa*, *Ruksha*, *Guru*, *Picchila*, *Yogavahi Sheeta virya*, *Madhura vipaka* and *Tridosahara*¹⁵.

In this study, we will evaluate the comparative effectiveness of *Abhaya-Nagara Churna* and *Vasavleha*.

ABHAYA NAGAR CHURNA (TRIAL DRUG)

Abhaya (Haritaki)

Terminalia chebula (*T. chebula*), known as *Haritaki* or *Abhaya* in Ayurveda belongs to Combretaceae family. It is also called as black myrobalan, chebulic myrobalan, *harada*, ink tree, or, *haritaki*¹⁶.

Phytochemical properties

Haritaki, contains several chemicals like amino acids, tannins, flavonoids, sterols, resin, fixed oils etc. It is especially rich in various tannins which make up to 32% of the chemical constituents of

haritaki. Chebulagic acid, chebulic acid, chebulinic acid, gallic acid and ellagic acid are the major tannins present in *haritaki*¹⁶.

Presence of triterpenoids and their glycosides are also reported in stem bark of *Haritaki*. According to some recent studies, *Haritaki* also contains more phenolics than compared to any other plant¹⁶.

Pharmacological Action of Abhaya

1. Anti-bacterial Action

- I. Gallic acid and Ethyl ester present in *haritaki* were found to work against *Staphylococcus* that is methicillin resistant¹⁷.
- II. *Abhaya* is also reported to be effective against *Helicobacter pylori*, which is mainly responsible for ulcer, gastritis and stomach cancers. It inhibits the urease activity of *Helicobacter pylori* (*H. pylori*)¹⁸.
- III. The ethanolic extract of fruit of *haritaki* was also found effective against both gram-positive and gram-negative bacteria, thus, it can act as a broad-spectrum antibiotic¹⁹.

2. Adaptogenic and Anti-Anaphylactic Action

- I. In a study, *T. Chebula* was found to reduce serum histamine levels²⁰.
- II. *T. chebula* acts against tumour necrosis factor-alpha produced due to influence of IgE in rat peritoneal mast cells through its water-soluble components, indicating its strong anti-anaphylactic action²⁰.

3. Anti-Inflammatory Action

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T. chebula shows anti-inflammatory action by inhibiting nitric oxide synthesis²¹.

4. Anti-allergic action

A polyherbal formulation known as Aller-7 consisting seven medicinal plants, including *Haritaki*, exhibited potent anti-allergic activity in isolated guineapig ileum substrate²².

5. Immunomodulatory Action

I. While *T. chebula* did not stimulate T-cells mediated immunity, it has a positive response on cell-mediated immune response²³.

II. A delayed and highly reduced hypersensitivity reaction and an increase in humoral antibody was found due to action of aqueous extract of *Haritaki*²⁴.

6. Anti-Oxidant Action

I. *T. chebula* was found to exhibit anti-lipid peroxidation and free radical scavenging activities²⁵.

II. Aqueous extract of *T. chebula* prevented reactive oxygen species (ROS) to act against anti-oxidant enzymes²⁶.

III. Ethanolic extract was found to possess anti-oxidant action by reducing lipid peroxidase²⁷.

IV. Triethylchebulate was to possess strong anti-oxidant action and free radical scavenging properties as it demonstrated strong DPPH free-radical scavenging ability²⁸.

Shunthi

Zingiber officinale belongs to *Zingiberaceae* family, and it has preventive effect on various disease like asthma, rheumatism, catarrh, diabetes etc²⁹.

Phytochemical properties

Z. officinale constitutes volatile oil rich in zingiberol, zingiberene, linalool, phellandrene which are responsible for the distinct aroma of ginger. The major compounds responsible for pungent nature of ginger are the gingerols, shogaol, zingerone and paradol²⁹. 6-gingerol and 6-shogaol are chemicals present in ginger responsible for antipyretic, analgesic, antitussive and hypotensive effects²⁹. Gingerdione inhibits the formation of 5-hydroxyeicosatetraenoic acid (5-HETE) and the prostaglandin-E2 (PGE2) from arachidonic acid, shogaol are preferential antagonist to 5-HETE formation and gingerol and dehydroparadol causes the inhibition of cyclooxygenase²⁹.

Pharmacological Action of Shunthi

1. Anti-Inflammatory

I. Shunthi exhibited anti-inflammatory and anti-platelet aggregation activities as it causes inhibition of the prostaglandin biosynthesis by acting against prostaglandin synthetase enzyme³⁰.

II. Ginger has a similar therapeutic effect as NSAIDs, as both suppress the synthesis of prostaglandin through the inhibiting cyclooxygenase-1 and cyclooxygenase-2. However, *shunthi* has a distinguishable effect on inhibiting 5-lipoxygenase, which results in suppression of leukotriene biosynthesis. Thus, it may have a better therapeutic effect than NSAIDs without the side effect of NSAIDs³⁰.

III. Gingerols, along with [8]-paradol, were found to be more potent anti-platelet and inhibitor of cyclo-oxygenase-1 (COX-1) than aspirin³¹.

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IV. [6]-gingerol, causes inhibition of macrophage activation through inhibition of cytokines which are pro-inflammatory markers and antigen presentation by macrophages³¹.

2. Anti-oxidant Action

I. Oleoresins and Ginger oil caused marked free radical scavenging activity in a concentration dependent manner³².

II. Many reports emphasize that the phenolic group such as shogaols, eugenol, gingerdiols, gingerols, zingerone, diacetoxy-[6]-gingerdiol, etc., may be responsible for their antioxidant properties³².

3. Anti-Bacterial Action

I. The antibacterial effect of essential oil of ginger is comparable to streptomycin while it was observed better than chloramphenicol for the tested bacterial strains³².

MATERIALS AND METHODS

AIMS AND OBJECTIVES

This study aims to compare the effectiveness of *Abhaya-Nagara churna* and *Vasavleha* in the management of *Tamaka Swasa* ~ Bronchial Asthma. The primary objective of this study will be to compare the efficacy of *Abhaya-Nagar churna* and *Vasavleha* on Forced expiratory volume in 1 second (FEV₁), Absolute Eosinophil Count, ACT (Asthma Control Test), ESR, AQLQ score. The secondary objective of this study will be to compare the efficacy of *Abhaya-nagar churna* and *vasavleha* in the management of the alleviation of *Swasa vega* (asthma attack),

Swasakrucchrata (dyspnoea), *Ghurghuruka* (wheeze), *Kasa* (cough), *Aseno labhate saukhyam*, *Pranavaha sroto dushti lakshan*.

Study design and Setting

This study is designed as a single-centred, open-label, randomized comparative parallel clinical trial. The diagnosed participants (known cases) attending the OPD and IPD of the Department of kayachikitsa, Ch. Brahm Prakash Ayurved Charak Sansthana, Khera, Najafgarh, New-Delhi-73, will be enrolled. Data will be recorded in special research proforma by personal interview and examination.

Sample Size

This study includes a total of 60 participants with a sample size of 30 in each group divided randomly irrespective of gender, cast, and religion.

Inclusion Criteria

- Patients between 18-60 years of age, irrespective of gender, cast, and religion will be included.
- Patients with mild and moderate cardinal symptoms (according to GINA).
- Patients who had a history of recurrent symptoms for more than six months.
- Subjects who are ready to give consent for trial with firm residential address and contact numbers.

Exclusion Criteria

1. Asthmatics who have a severe attack (according to GINA).
2. Patients with other systemic disorders.

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3. Other complicated respiratory disorders like COPD, bronchiectasis, TB, etc.
4. Pregnant women and lactating mother.
5. Patients addicted to smoking.
6. Subjects with known hypersensitivity to any of the contents of *Abhaya Nagar churna*, or *Vasavleha*.

Withdrawal Criteria:

The subject will be withdrawn from the trial if:

1. Patient develops any adverse effect.
2. There is non-compliance to treatment or there is any other serious physical or mental problem that may hinder adherence to trial.
3. The condition of the subject deteriorates during course of treatment.
4. He or she wants to withdraw from the trial.
5. Patients not giving proper follow-up.

Primary Assessment Criteria

- Forced expiratory volume in 1 second (FEV₁)
- Absolute Eosinophil Count

Table 2 Posology of Control and Case

Group	Sample Size (No.)	Intervention	Dose (grams) and Frequency	Anupana
Group A	30	<i>Vasavleha</i>	12 gm, 2 times after meal	<i>Ushna jala</i>
Group B	30	<i>Abhaya-Nagara churna</i>	3gm- <i>Abhaya</i> 1gm- <i>Nagara</i> , 2 times after meal	<i>Ushna jala</i>

Duration of Trial:

- Intervention of *Vasavleha* and *Abhaya Nagar kalka*: 28 days
- Follow up: 30 days
- Timeline of intervention: 1-28th day

Statistical Analysis:

Statistical analysis will be carried out to obtain the percentage relief to assess the efficacy of the therapy. The data generated in the clinical study

- ACT (Asthma Control Test) Score
- ESR
- AQLQ Score

Secondary Assessment Criteria

- *Swasa vega* (asthma attack)
- *Swasakrucchrata* (dyspnoea)
- *Ghurghuruka* (wheeze)
- *Kasa* (cough)
- *Aseno labhate saukhyam*
- *Pranavaha sroto dushti lakshana*

Grouping And Posology

i. Grouping

2 group each with a minimum of 30 patients who are fulfilling the criteria for inclusion as mentioned in Table 1.

Table 1 Grouping of Drugs

Group	Group A	Group B
Sample Size	30	30
Intervention	<i>Vasavleha</i>	<i>Abhaya-Nagar churna</i>
Intervention Done	Twice daily for 28 days	Twice daily for 28 days

ii. Posology

Mentioned in Table 2

will be analysed by applying appropriate statistical method. Data will be analysed at the end of study period by using the appropriate "Students t-test" or ANOVA test. The results will interpret as:

- Significant $p < 0.05$
- Insignificant $p > 0.05$

Plan of Study

As mentioned in Table No. 3

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Table 3 Plan of Study

Title	A comparative study to evaluate the effectiveness of <i>Abhaya-Nagara Churna</i> and <i>Vasavleha</i> in Management of <i>Tamaka swasa</i> ~ Bronchial Asthma.					
Steps	DAY 0	DAY01	DAY07	DAY14	DAY28	DAY 29-50
SCREENING						
HISTORY AND PHYSICAL EXAMINATION						
Drug intervention	1-28 day					
ASSESSMENT OF SYMPTOM SEVERITY OF DISEASE						
AQLQ SCORE						
ACT SCORE						
ESR, AEC						
FOLLOW UP						

DISCUSSION

With global warming and dwindling quality of air, especially in cities like Delhi, which is ranked as one the most polluted city in the world, the cases of respiratory disorders are escalating every passing year. As the primary contributor to bronchial asthma or *Tamaka swasa* are dust, smoke and allergens or pollutants in the environment, more and more individuals are getting sensitized, resulting in an increased incidence of Bronchial asthma in developing countries and major cities. The world is amid a pandemic currently, with an ever-increasing list of COVID and post-COVID complications, especially respiratory complications like chronic cough, dyspnoea etc., thus, selecting this topic become even more relevant.

Tamaka Swasa is a clinical condition involving *pranvaha srotas dushti* by *partiloma Vata* and *avrudha Kapha* results in *Shwasa krucchrata* (dysnoea), with symptomatic similarities to Bronchial Asthma¹. The trial drug selected for this study includes administration of *Haritaki* and *shunti* in a ratio of 3:1, that is, 3 grams of

Haritaki powder with 1 gram of *Shunti powder* with warm water twice daily. The comparator opted for this study is *Vasavleha*, due to extensive work done of its effect in respiratory disorders.

Haritaki is *Kashaya pradhana pancharasa, ushna* and *tridosha shamaka*. It has *kanthya* and *swarya* effect on *pranvaha srotas* and specifically mentioned in *swara vicar, swasa, kasa* and *rajyakshama*⁷. According to *Charaka*, *Haritaki* is *Doshaanulomni* and it's also *Vata hara*, thus it may lead to *anulomana* of *Vata*. It is also mentioned that it swiftly abolishes *srotovibandha* and *pralepa*(~Congestion) of *hridaya and urha Pradesh* (thoracic region)⁸. Thus, it can nullify the *Kaphavibandha* which causes *pratiloma gati* of *Vata* which are basic pathognomonic characteristics of *swasa*. Further, *Haritaki* has also *Rasayana* properties, it has anti-oxidative activity, adaptogenic and anti-anaphylactic activities, cytoprotective activity and immunomodulatory activity³³.

Shunti, is *katu rasa, Madhura vipaka, ushna virya* and *Vata-Kapha ghana*. It has *laghu*,

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*snigdha and Vata anulomana karma*⁹. Thus, it is also an ideal drug to nullify the *samprapti* of *swasa* by causing *Vata-Kapha shamana* and *anulomana* of the *pratiloma Vata*. The rhizome of ginger is potent inhibitor against prostaglandin biosynthesizing enzyme which is associated with anti-inflammatory and anti-platelet aggregation activities³⁴.

Vasa avaleha is mentioned in *Bhaishajya Ratnavali Kasa Roga Chikitsa*¹⁰. *Vasa* (*Adhatoda vasica*) is *Tikta rasa, Ruksha, Sheeta virya, Katu vipaka* and *Deepana, Anuloman*¹¹. *Pippali* (*Piper Longum*) is *Katu rasa, Ruksha, anushnasheeta, Madhura vipaka* and *Deepana, Anulom*¹². *Sita* is *Madhura rasa, Snigdha, Sheeta virya, Madhura vipaka* and *Vatahara, Dhaturvidhakara*¹³. *GoGhrita* is *Madhura rasa, Snigdha, Guru, Sheeta virya, Madhura vipaka* and *Tridosahara*¹⁴. *Madhu* is *Kashaya-Madhura rasa, Ruksha, Guru, Picchila, Yogavahi Sheeta virya, Madhura vipaka* and *Tridosahara*¹⁵.

Vasa (*Adhatoda vasica*), *Pippali* (*Piper longum*), *Madhu* (honey) have *Sukshma, Tikshna guna* which eliminate the *Upalepa* of *Kapha* in *Kantha* (throat) and *Ura* (chest) and cause *Kaphanihsarana*. *Sita, Go-Ghrita* (cow ghee), *Pippali* are *Vatahara* drugs, which results in *Vatanulomana* and pacification of *Vimargami vridhdha Vata*. As *Tamaka Swasa* is a *Pittasthana vyadhi*, *Go-Ghrita* and *Pippali* also act on the *adhithana* of the *vyadhi* thus improving the function of *Agni* and normalizing action of *Vata*. This process improves the assimilation, digestion and metabolism. Further, *Go-ghrita* and

Pippali are *Rasayana* (rejuvenative), thus they assert their immunomodulator effect and prevent the recurrences of symptoms³⁵.

Vasa which is the major ingredient in *Vasavleha*, is indicated in *Shwasa* (*Bronchial Asthma*), *Rajayakshma* (tuberculosis), *Raktapitta, Shotha* (edema), and *Jwara* (fever)³⁶. The alkaloids in *Vasa*, *Vasicine* and *vasicinone*, are broncho-dilatory in nature³⁷.

Pippali enhances bioavailability which results in prolonged availability of the major active therapeutic principle in the systemic circulation which causes the anti-asthmatic activity of the formulation³⁸.

Thus, both the drug selected for this study will help in *samprapti vighatana*. As *Tamaka Swasa* is a *Vata-Kaphajja vyadhi*, both the drug enlisted in the study and their component act on the major *dosha, dushya* and *vyadhi aadhithana*. The drug is expected to decrease the number of *shwasa vegas* and relieve the dyspnoea. It is also expected to reduce the dependency of patients on inhaler and provide a better quality of life to the asthmatic patient.

Follow-up of 30 days will be done to monitor any adverse effect of the drug and the recurrence of the disease symptoms.

CONCLUSION

The study shows the comparison between two treatment modalities of Ayurveda wherein the efficacy of *Abhaya Sunthi Churna* will be studied in comparison with *Vasavleha*. This study also

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analyzes the efficacy of Ayurveda treatment modalities on hematological and biochemical parameters in bronchial asthma.

FINANCIAL SUPPORT

Nil.

CONFLICT OF INTEREST

There are no conflicts of interest.

ETHICAL CONSIDERATION

The study is IEC approved and registered under CTRI with registration number as: CTRI/2022/04/042167.

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