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CLINICAL STUDY ON THE EFFECT OF *SOUVARCHALADI CHURNA* AND *KARNAVEDHANA ON TAMAKA SHWASA* WITH SPECIAL REFERENCE TO BRONCHIAL ASTHMA

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ABSTRACT

Background: Asthma is a widespread chronic, non communicable disease, affecting millions globally and causing thousands of death each year. *Tamakashwasa* is often equated with Bronchial Asthma due to their similar symptoms. Modern asthma treatments are effective but may cause long-term side effects. Ayurvedic medication have fewer side effects but are often avoided due to cost, taste, or neglect after improvement. Many urban patients seek alternatives, and *Karnavedhana* is a good option for early-stage, mild asthma. **Methodology:** In present setting of clinical study, total 60 cases of Bronchial Asthma which were fulfilling the diagnostic criteria, were registered from OPD and IPD of *Kayachikitsa*, S.S. hospital, BHU, Varanasi. Patients were randomly divided into three groups with 20 patients each. One group of pateints received only Ayurvedic drug '*Souvarchaladi Churna'* as intervention and Second group of patients received only *Karnavedhana* Therapy whereas Third group received both intervention '*Souvarchaladi Churna and Karnavedhana'*. **Observation and Results:** It was obeserved that All three groups are significantly

improved PFT values and symptoms with P value <0.001. The study shows the superiority of *Karnavedhana therapy* with *Souvarchaladi Churna* over S*hamana* and *Karnavedhana* alone due to its synergistic effect. **Conclusion:** Due to wider range of action, *Karnavedhana* therapy with *Souvarchaladi Churna* shown better results. Moreover, no side effects were obtained during and after treatment.

KEYWORDS: *Karnavedhana, Souvarchaladi Churna, Tamakashwasa,* Bronchial Asthma.

1. INTRODUCTION

With rising pollution, more people are suffering from lung diseases each day. As of the 2022 Global Asthma Report, asthma affects 262 million people globally, including 30-35 million in India, accounting for 13.09% of the global burden and nearly a third of related deaths.[1] Bronchial Asthma is defined as chronic inflammatory disorder of airways which manifests itself as recurrent episodes of wheezing, breathlessness, chest tightness and cough due to hyper-responsive bronchi and airflow obstruction, generally reversible spontaneously or with treatment. Global initiative for asthma(GINA) have mentioned the following categories of medications for the management of asthma Short and Long acting beta agonists, Corticosteroids, Leukotriene receptor antagonists, IgE Immunomodulators etc. These are effective but may cause side effects like tremors, insomnia, and nervousness etc.[2]

In Ayurveda, breathing disorders are called Shwasa Rogas. Types include: *Maha Shwasa, Urdhva Shwasa, Chhinna Shwasa, Tamaka Shwasa, Kshudra Shwasa. Tamaka Shwasa* is merely considered as Bronchial Asthma as symptoms are same in this type as mentioned above. *Tamaka Shwasa* is '*Yapya vyadhi*'[3] in the point of prognosis means a disorder in which medicine is to be taken for whole life to prevent exacerbations of the disease and to prevent episodic symptoms. *Shwasa* is a *Kapha-Vata* disorder originating from *Pittasthana*. It occurs when *Kapha* obstructs *Prana Vayu,* causing vitiated *Vayu* to flow against its natural course (*Pratiloma),* leading to breathlessness. The formation of *Ama* and obstruction in *Pranavaha Srotas* by *Kapha* trigger these symptoms, which resolve once the obstruction is cleared and *Vayu* flows normally. *Ayurveda* describes two type of management of all disease i.e. *Shodhana* (purification & excretion of vitiated *Doshas* out of body) & *Shamana Chikitsa.*[4][5]

Conservative management of asthma with modern medicine is effective but has long-term side effects. *Ayurvedic* treatments are also effective with fewer side effects, but patients often

avoid them due to cost, unpleasant taste, or negligence after improvement. Urban asthma patients are aware of their condition but seek alternatives to lifelong *Ayurvedic* medication. *Karnavedhana* is a viable option for those in the early stages of asthma with mild symptoms. Considering the *Ayurvedic* concept of treatment of *Tamaka shwasa* it was decided to select *herbal* preparations '*Souvarchaladi Churna' and Karnavedhana Therapy.* in the management of bronchial asthma. The drugs were decided to give through oral route.

2. METHODOLOGY

2.1 Aim and objective of the Study

The study aims to clinically evaluate the efficacy of "*Souvarchaladi Churna*" and "*Karnavedhana"* in managing *Tamaka Shwasa.* Its objectives include exploring Ayurvedic descriptions of breathing disorders with a focus on *Tamaka Shwasa*, analyzing Ayurvedic and contemporary scientific approaches to its management, and understanding the modern medical concept of bronchial asthma and its treatment limitations. The study further seeks to assess and compare the effectiveness of *Souvarchaladi Churna* and *Karnavedhana* in treating *Tamaka Shwasa.*

2.2 Permission and Registrations

The trial protocol and related documents were presented before the Institutional Ethical Committee as a synopsis. The committee had provided the approval to work with the reference number **Dean/2022/EC/4006.**

The trial has been registered in the clinical trial registry of India **(CTRI No. CTRI/2023/06/054480)**

2.3 Study design and patient grouping

The study enrolled 60 patients with *Tamaka Shwasa*, randomly divided into three groups of 20 each in a randomized, open-label, parallel-arm clinical trial lasting two months. Group A received *"Souvarchaladi Churna"* (5 gm twice daily) with lukewarm water as *Anupana*, with follow-ups every 15 days. Group B underwent *"Karnavedhana Therapy*" with the same follow-up schedule. Group C was treated with *"Karnavedhana Therapy*" followed by "*Souvarchaladi Churna"* (5 gm twice daily) with lukewarm water, also followed up every 15 days. Upon completion, the data from all 60 patients were statistically analyzed to evaluate the efficacy of the treatments.

2.4 Preparation of Souvarchaladi Churna

Souvarchaladi Churna was prepared using *Souvarchala Lavana* (Black Salt), *Nagar* (Zingiber officinale), *Bharangi* (Clerodendrum serratum), and Sugar in a 1:1:1:2 ratio. The ingredients were identified according to the Ayurvedic Pharmacopoeia of India (API) and sourced from GMP-certified herbal manufacturers. The formulation was verified by experts from the *Dravya Guna* and *Ras Shastra* Department, Faculty of Ayurveda, I.M.S., B.H.U., and the dry ingredients were ground and thoroughly mixed.[6]

2.5 *Karnavedhana* Procedure and Postoperative Care

The *Karnavedhana* procedure was performed using a sterile silver needle designed with a pointed end and a loop for fixing as a ring. Instruments included sterile gloves, kidney tray, gauze pieces with betadine and spirit, and a flashlight. The procedure involved piercing the *Daiv Krit Chhidra*[7][8] (a small, avascular spot in the concha) of the external ear, typically the left ear for convenience, under aseptic conditions. The ear was cleaned with spirit and betadine, and the spot was illuminated with a torch for accuracy. The needle was briskly inserted and left in place as a ring without causing blood loss.[9] The pierced site was covered with sterilized cotton to prevent infection.

Postoperatively, patients were advised to apply warm mustard oil mixed with turmeric powder to the site and move the ring daily for 8–10 days. Afterward, the silver ring could be replaced with a silver or gold nose pin to be worn for life. Follow-ups were scheduled every two weeks, with standard asthma treatment provided in case of recurrence.

Dietary advice included consuming fresh, warm, light, and nutritious food while avoiding fried, fatty, and cold items, as well as smoking, alcohol, and allergens for 45 days. Patients were also instructed to avoid exposure to dust, smoke, and cold winds and to keep the pierced ear dry. Non-compliance with these instructions was discouraged.

2.6 Criteria for selection

All cases were selected from OPD/IPD Department of Kayachikitsa. S.S. Hospital, IMS BHU, Varanasi.

2.6.1. Inclusion criteria

The study included patients aged 18 to 60 years of either sex who were willing to participate. Eligibility criteria required a history of Tamaka Shwasa for less than five years and

presentation with its classical features. Patients with a peak flow meter rate between 80 and 300 liters/min, Forced Vital Capacity (FVC) and Forced Expiratory Volume in one second (FEV1) between 60% and 80%, and an FEV1/FVC ratio between 5% and 20% were considered for inclusion.

2.6.2. Exclusion criteria

The study excluded patients unwilling to participate, those below 18 or above 60 years of age, and those with a history of *Tamaka Shwasa* exceeding five years. Pregnant and lactating women, as well as individuals with conditions such as emphysema, bronchial carcinoma, pleural effusion, neurological disorders (e.g., epilepsy, hemorrhagic stroke, meningitis), psychological disorders, or tuberculosis, were not included. Patients with status asthmaticus, diabetes mellitus, hypertension, occupational or cardiac asthma, and those requiring emergency oxygen inhalation were also excluded from the study.

2.6.3. Objective assessment criteria

The assessments included Pulmonary Function Tests (Spirometry) measuring Forced Expiratory Volume in the first second (FEV1), Forced Vital Capacity (FVC), and Peak Expiratory Flow Rate (PEFR). Additional evaluations included Vital Capacity, Absolute Eosinophil Count, Complete Blood Count (CBC), and Erythrocyte Sedimentation Rate (ESR).

2.6.4. Subjective assessment criteria

Scoring method was adopted for various subjective features like -Frequency of *Shwasavega*, Duration of attack, *Shwasa kricchrata, Asino labhate soukhyam, Kasa* (cough), *Kapha nishtivanam* (expectoration), Rudhho Ghur-ghurakam (wheezing), Peenasa (running nose), Urashoola (chest pain).

The clinical gradations of symptoms were as follows.

0 : No symptoms present

1 : Mild symptoms present

2 : Moderate symptoms present

3 : Severe symptoms present

Dyspnea (Breathlessness) Modified Medical Research Council (mMRC).[10]

2.7 Statistical analysis

The results were statistically analysed using Wilcoxon signed rank test, Kruskal walis test and final conclusion were drawn.

3. OBSERVATIONS AND RESULTS

The findings of the data of observation and results were organized under the following headings.

3.1. Demographic Profile

Among total registered patients, maximum was in the age group 21-40 years (55%), 61.7% were males, 91.7% were Hindu by religion, 78.3% belonged to middle class socio-economic group, 50% have completed senior secondary education, 33.3% by service men/women by occupation, 73.3% were married, 65% belonged to urban area by habitat, 73% patients were having family history of bronchial asthma, 81.7% were not addicted to any substance.

3.2. Constitutional Profile

Among total registered patients, maximum no. of patients i.e 68.3% were of *Vata-shleshma Prakrit.*[8] 73.3% were of *Rajsika-tamsika,* 56.7% were of *Avara Vyayama Shakti,* 70% were *of Madhyam Pramana.*

3.3. Therapeutic Profile

The data of FVC (forced vital capacity) shows that the initial mean and SD in Group A was 60.50± 11.98 after 2 months of trial treatment it was shifted to 64.90±12.05. In Group B initial mean and SD was 56.30±12.53 after 2 months of trial treatment it was shifted to 66.70±11.83. In Group C initial mean and SD was 54.90±10.13 after 2 months of trial treatment it was shifted to 68.70±9.137 **(Table 1 and Fig 1)** In all three groups improvement was statistically highly significant (p=0.000). When intergroup comparisons (paired 't' test) is done, the changes in FVC are not significant BT & AT.

FEV_1 : The data of FEV_1 (forced expiratory volume in 1 second) shows that the initial mean and SD in Group A was 59.00 ±12.22 after 2 months of trial treatment it was shifted to 64.75±12.39. In Group B initial mean and SD was 55.25±13.38 after 2 months of trial treatment it was shifted to 66.25±13.68. In Group C initial mean and SD was 55.20±12.03 **(Table 2 & Fig 2)** after 2 months of trial treatment it was shifted to 69.05±8.256. In all three

groups improvement was statistically highly significant (p=0.000). When intergroup comparisons (paired 't' test) is done, the changes in FVC are not significant BT & AT.

PEFR: The data of PEFR (peak expiratory flow meter rate) shows that the initial mean and SD in Group A was 55.85±13.92 after 2 months of trial treatment it was shifted to 61.20±13.24. In Group B initial mean and SD was 63.90±17.50 after 2 months of trial treatment it was shifted to 76.60±13.48. In Group C initial mean and SD was 58.55±12.30 after 2 months of trial treatment it was shifted to 73.40±12.53 **(Table 3 & Fig 3)** In all three groups improvement is statistically highly significant (p=0.000). When intergroup comparisons (paired 't' test) is done, the changes in PEFR are not significant BT & AT.

Vital Capacity: The data of VC (vital capacity) shows that the initial mean and SD in Group A was 870.0±192.2 after 2 months of trial treatment it was shifted to 1042.1±153.8. In Group B initial mean and SD was 870.0±192.2 after 2 months of trial treatment it was shifted to 1095.0±146.8. In Group C initial mean and SD was 840.0±208.7 after 2 months of trial treatment it was shifted to 1095.0±146.8. In all three groups improvement was statistically highly significant (p=0.000) **(Table 4 & Fig 4)** When intergroup comparisons (paired 't' test) is done, the changes in PEFR are not significant BT & AT. The data of Wheezing also shows statistically significant improvement with a p value <0.005 before and after treatment in both groups. The data of Respiratory rate shows statistical improvement only in Group C (p=0.00)

3.4. Clinical Profile

There was significant remission in severity of symptom in all three groups after treatment. But patients of Group C treated with '*Karnavedhana* therapy along with *Souvarchaladi Churna'* show better in most of symptom in terms of shifting of grades from severity to normal one. Within the group comparison (Wilcoxon Signed Rank Test) the improvement was also statistically significant *viz*. Frequency of *Shwasa vega* p= 0.000, Duration of attack p=0.000, *Kasa* (cough) p=0.000, *Kapha Nishthivanam*(expectorant) p=0.000, *Ruddho Ghurghurkam* (wheezing) p=0.000, *Peenasa* (running nose) p=0.002, Dyspnea p=0.000. Group C had 45%, Group B had 25% and Group A had 15% marked improvement in the symptoms. Group C had 30%, Group B had 35% and Group A had 25% moderate improvement in the symptoms. Group C had 25%, Group B had 40% and Group A had 60% mild improvement in the symptoms respectively. It was observed that Group C got more marked & moderate improvement but Group A got more mild improvement. The overall improvement was higher in Group C as compare to Group B and Group A. On the basis of

above observations, it is concluded that Group C shows better results in most of symptoms except *Shwasakricchrata* after that Group B and then Group A (Group C >Group B > Group A).

Overall Improvement based on clinical Symptoms

The following Criteria were used for improvement of over symptoms.

Table 5: Showing Overall Improvement.

Overall Improvement	Absence of symptoms AT
Marked Improvement	75-100%
Moderate Improvement	50-75%
Mild Improvement	0 -50%

3.5. Laboratory (Safety Profile)

In Group A, there are not significant changes in TLC, ESR, AEC, AST, ALT, T.B, Creatinine, RBS. But the changes seen within normal range. In Group B and Group C shows decrement in mean±SD of TLC, ESR, AEC which is statistically significant. Other parameters AST, ALT, T.B, Creatinine, RBS there are not significant changes which lies within normal range.

4. DISCUSSION

4.1. Probable mode of action of drug

In this trial, the selected drugs, guided by Ayurvedic pharmacodynamics *(Rasa, Guna, Veerya, Vipaka),* provide *Deepana-Pachana* effects, preventing *Aama* formation and enhancing digestion. They target *Kapha,* clearing obstructions in the *Pranvaha Strotasa,* thus allowing *Vata* to move in its natural *Anuloma* direction.[11] With their *Katu, Tikta Rasa* and *Ushna Veerya*, the formulation acts as a bronchodilator and expectorant, pacifying *Kapha* and *Vata Dosha.* The *Teekshna* and *Ruksha Guna* further aid in *Kapha* expulsion through *Chhedana,* making this combination effective in managing *Tamaka Shwasa.* The anti-asthmatic effects of *Souvarchaladi Churna* can be explained through its active ingredients.[12]

Souvarchala Lavana: Exhibits anti-inflammatory and mucolytic properties.[13]

Sunthi: Offers antimicrobial, anti-inflammatory, and antioxidant benefits.[14]

Bharangi: Provides anti-histaminic, bronchodilator, mast cell stabilization, and anti-allergic effects by ingredient soponin.[15] This combination effectively addresses the pathology of

asthma by removing *Aavaran* (obstruction) caused by *Kapha* and *Pitta* while promoting the *Anuloma* movement of *Vata*[16], contributing to its anti-asthmatic properties.[17]

4.2. Probable mode of Action of *Karnavedhana* therapy

Karnavedhana therapy, an ancient practice of ear piercing, exert therapeutic effects through vagus nerve stimulation. The auricular branch of the vagus nerve, which supplies the area around the external auditory meatus, has connections to the respiratory system, including the trachea and bronchi.[18] The vagus nerve carries parasympathetic fibers that influence bronchoconstriction and bronchodilation. By stimulating the auricular branch, *Karnavedhana* activate parasympathetic pathways that promote bronchodilation.[19] This process occurs through the release of acetylcholine, which binds to cholinergic receptors and counteracts bronchoconstriction. Additionally, the Non-cholinergic Non-adrenergic (NANC) inhibitory fibers associated with the vagus nerve contribute to bronchodilation. This combined effect help relax the airways, making it easier to breathe, which benefit individuals with chronic respiratory conditions like asthma by reducing bronchospasms. *Karnavedhana* therapy, by stimulating the vagus nerve, indirectly activate bronchodilator pathways, offering potential relief for patients with chronic bronchoconstriction, such as those suffering from asthma. If *Karnavedhana* is performed on both ears at the concha, it could enhance the therapy's efficacy by providing balanced stimulation of vagus nerve in both ears. This may result in improved bronchodilation, enhanced respiratory function, and better management of symptoms of asthma.

5. CONCLUSION

In Ayurveda, *Tamaka Shwasa* closely aligns with bronchial asthma, a growing health challenge due to environmental changes, poor diet, and allergen sensitivity. While modern medicine manages acute asthma effectively, its long-term side effects prompt a need for better solutions. This study evaluated Karnavedhana therapy and Souvarchaladi Churna, showing significant improvement in lung function (FVC, FEV1, and PEFR), with the combined therapy (Group C) yielding the best results. Souvarchala Lavana, Sunthi, and Bharangi provided anti-inflammatory, bronchodilatory, and anti-allergic effects, while Karnavedhana stimulated cholinergic fibers, enhancing bronchodilation. The combined approach proved cost-effective, side-effect-free, and superior to individual therapies, offering a promising alternative for chronic asthma patients.

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