

Clinical efficacy of herbal *Padmapatradi yoga* in bronchial asthma (*Tamaka Swasa*)

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ABSTRACT

Ayurveda refers to bronchial asthma as *Tamaka Swasa* and it is well explained in *Charaka Samhita*. It contributes several modalities of the treatment for Swasa roga (asthma). Among all modalities of treatment, polyherbal combinations are said to be well-accepted, safe and effective in asthma. A study was carried out in 40 patients of either sex in between the age of 15-65 years to assure the clinical response of *Padmapatradi yoga* in bronchial asthma (*Tamaka Swasa*) at P.G. department of Kayachikitsa, D.G.M. Ayurvedic Medical College, Gadag, Karnataka. The sum total properties of *Padmapatradi yoga* is *tikta katu rasa*, *laghu and tikna guna* (light and penetrating properties), *ushna virya* (hot potency) and *vatakaphagna* (decrease vata and kapha dosa) *Padmapatradi yoga* is effective in increased peak expiratory flow rate, breath holding time, and reduces the absolute eosinophil count of studied cases and also found statistically highly significant at $p < 0.001$ level. The drug is quite safe and acts as a bronchodilator, antihistaminic and anti-inflammatory.

Key words: Breath holding time, bronchial asthma, dyspnea, forced expiratory volume, *Padmapatradi yoga*, peak expiratory flow rate, *Tamaka Swasa*, vital capacity

INTRODUCTION

Bronchial asthma is a chronic inflammatory disorder of the airway and the most common distressing disease affecting 3-5% of the total population.^[1] In 1998, the national asthma campaign estimated the prevalence of diagnosed asthma cases in India to be 3.4 million.^[2] In the field of allergic respiratory diseases, several indigenous drugs have been successfully tested and used as conservative therapy in asthma. Ayurveda, the great indigenous system of medicine of India is a complete healthcare system and deals with the preventive and curative aspect of many diseases. Ayurveda refers to bronchial asthma as *Tamaka Swasa* and contributes

several modalities of treatment for the same.^[3] Among all the treatment modalities polyherbal combinations are said to be well-accepted, safe and effective in asthma.^[4] The reason for the therapeutic efficacy of herbal combinations in asthma is due to multiple blocking and homeostasis of very complex and interdependent cellular and mediator networks supporting and involved in the inflammatory process of asthma, whereas modern synthetic drug therapy aimed at blocking one mediator alone would be unlikely to have any significant effect on the disease process. None of the available treatments are found to be effective to provide a complete cure of this disease.^[5]

The goal of asthma treatment has shifted from symptom relief to disease control and it also ensures the patient's wellbeing.^[6] Herbal preparations have been cited as the third most popular complementary treatment modality.^[7] Sometimes herbal remedies increase the morbidity and adherence to inhaled corticosteroids.^[8] But *Padmapatradi yoga*.^[9] is an experience-based polyherbal compound having five herbs i.e. *Padmapatra* (*Inula recemosa*), *Bhargi* (*Clerodenum serratum*),^[6] *Malaya Vacha* (*Alpinia galanga*), *Shati* (*Hedychium Spicatum*), and *Pippali* (*Piper longum*). All the drugs have *ushana virya* (hot potency) and *Vata kapha hara* properties, which is the main dosa in asthma. There are many evidences of these herbal constituents of *Padmapatradi yoga*.^[10] *Inula recemosa* can produce relaxation of bronchioles like adrenalin, but action was

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less powerful and took a longer time to develop and also persisted for a longer period. *Hedychium spicatum* and *Clerodendrum serratum* are said to possess anti-inflammatory and antihistaminic properties.^[11-15] *Piper longum* is a known immunomodulator drug. *Alpinia galanga* has a bronchodilatory and anti-inflammatory effect on bronchioles.^[16,17]

In this study, we propose to observe the effect of *Padmapatradi yoga* on bronchial asthma with the fixed subjective and objective parameters

MATERIALS AND METHODS

Patients

The study involved a total of 40 patients of either sex of bronchial asthma aged between 15-65 years. The study was carried out in the P.G. department of Kayachikitsa, D.G.M. Ayurvedic Medical College (DGAMC), Gadag, Karnataka.

Inclusion criteria

Patients above the age of 15 years and below the age of 65 years were included, irrespective of their sex, on the basis of clinical signs and symptoms. Bronchial asthma with a history for at least one year, nonsmokers and absence of long-term remissions of asthma (lasting more than one month) are included in the study.

Exclusion criteria

Patients with bronchial asthma with accompanying diagnosis of heart disease, other infectious disease, arterial hypertension and patients with chronic asthmatic bronchitis along with bronchiectasis were excluded from the study. Patients who had long-term history of smoking, abnormal baseline hematology, blood chemistry or urinalysis, and lactating mothers and pregnant ladies, patients on other therapies (allopathic, homeopathic or other than prescribed Ayurveda drugs) along with our trial drug and not willing for this herbal treatment were excluded. Written informed consent was obtained from each patient and the institutional ethical committee approved clinical protocol.

Study design and duration

The study design was open clinical trial of over 40 cases of bronchial asthma. The study was a preliminary attempt to know the efficacy of this formulation, therefore a control group was not taken. Moreover, the trial was in an Ayurveda hospital and administration of modern control was an ethical problem. The duration of treatment was one month.

Trial drug

All the ingredients of trial drug (*Padmapatradi yoga*) were well-identified by taxonomist [Table 1]. All the drug samples were preserved and kept in the museum of

DGAMC, Gadag. The drugs were dried and processed into powder form. No binding substance was added. The drug was prepared by Balagi Ayurveda Pharma, Bagalore. The High Pressure liquid chromatography (HPLC) of the tablets was done randomly to ensure that quality and good manufacture practice was followed. Total number of bacteria, pathogens, and aflatoxins are measured and found below the admissible limit.

Matra (Dose), *Ausadha sevan kala* (Drug administration time) and *Anupana* (vehicle)

The trial drug was delivered, in tablet form, each containing 500 mg. Every patient received four tablets or 2 g per day in two divided doses. However, the dosages were flexible according to *rogibala* (stamina of patient), *rogabala* (severity of diseases) and *vaya* (age) of the patient. The drug administration time was *prabhata prag bhukta* (morning before food, 7 am) and *sandhya prag bhukta* (evening before food, 7 pm). The *anupana* (vehicle) was *usna jala* (lukewarm water).

Assessment

All the patients were evaluated once a week for their states/ frequency of asthmatic attacks, status of expiratory dyspnoea, severity of cough, period of shortness of breath and reduced tolerance to the physical activities.^[18]

Forced expiratory volume in 1 second (FEV₁), peak expiratory flow rate (PEFR), breath holding time (BHT), and vital capacity were measured at the start and end of treatment.^[19] ECG and chest X-ray were done in all the patients. Absolute eosinophil count was also measured before and after treatment.

Method /Procedure to measure peak expiratory flow rate

The Wright peak flow meter was used to measure the PEFR. The patient was asked to take a deep breath and then to blow hard into the mouthpiece of the flow meter with a sharp blast. The movement of the needle on the dial indicates the PEFR in liters per minute. Six readings were taken at 1-min intervals, and the average of four higher readings was recorded. The needle was brought back to zero by pressing the button located near the mouthpiece. Normal range is 350-500 liters /min.

Procedure to measure breath holding time

The patient was asked to sit quietly for a few minutes, breathing normally, before the BHT exercises were started. The patient was asked to pinch his nostrils with the thumb and forefinger and hold his breath after a normal inspiration. The time for which the breath could be held was noted with stop watch. Observations were

made at intervals of 2 min. The highest figure for each determination in the BHT for that exercise.

Criteria for overall assessment of results

The overall assessment of results was made with the help of the below mentioned subjective and objective parameters.^[20]

Complete remission

- Total disappearance of sign and symptoms.
- No attack.
- No night awakening.
- $PEFR \geq 350$ l/m, $BHT \geq 40$ sec.

Major improvement

- Nature of attack from severe to mild.
- Frequency of attack one to two times for 15 days.
- No night awakening.
- Improvement in $PEFR \geq 250$ l/m, $BHT \geq 25$ sec.

Minor improvement

- Nature of attack severe to moderate.
- Frequency more than two times for 15 days.
- Night awakening present.
- Slight improvement in $PEFR \geq 150$ l/m, $BHT \geq 15$ sec.

No response

- No response in the nature of attack or increased.
- Frequency continues.
- Night awakening present.
- No response/ decrease in $PEFR$ and BHT .

Statistical analysis

Data was analyzed using the computer software of medical statistics “Epiinfo 6.02 issued by the WHO and CDC, USA. Levels of significance were calculated using student ‘t’ test and P value less than 0.05 was considered significant.

OBSERVATION AND RESULTS

It was observed that maximum patients (14, 35%) were from the age group of 45-55 years and male patients (26, 65%) were dominant in this study [Figure 1]. Before treatment, patients had attacks, expiratory dyspnoea, cough, and period of shortness of breath and reduced tolerance to physical activities. Ten (25%) patients had attacks of expiratory dyspnoea (*Shmashastvata*) every day, 20 (50%) once in two days and the remaining patients had symptoms two to three times per 15 days [Table 2]. Twenty-two (55%) patients had mucoid sputum and seven (17.5%) cases had purulent sputum; 11 (27.5%) had dry cough without sputum [Table 3]. The tolerance to physical activities was normal in 15 (37.5%) cases, reduced in 20 (50%) cases and severely reduced in five (12.5%) cases [Table 4]. It was

observed that 11 (27.5%) patients had severe attack, 19 (47.5%) patients had moderate and 10 (25%) patients had mild attack before treatment. Twenty-six patients (65%) had no attack or were free from attack during our study period, six (15%) patients had moderate asthma, six (15%) patients had mild asthma after treatment and two (5%) patients could not respond to our treatment [Table 5]. The maximum number of patients i.e. 22 (55%) had minimum $PEFR$ range (50-150) and three (7.5%) patients had high $PEFR$ range (>300) before treatment. It is interesting to note that 12 patients (30%) had normal $PEFR$ value (>350) and another 20 patients (50%) improved in the said value and two (5%) patients had no change in terms of $PEFR$ value [Table 6]. It was observed that 24 patients (60%) had BHT 0-15 sec, 13 patients (32.5%) had BHT 0-15 sec and three patients (7.5%) had BHT range 21-30 sec before treatment. After treatment 18 patients (47.5%) had normal BHT (>30 sec) and another 10 (25%) improved in BHT and of patients (5%) had no change in their BHT [Table 7]. The absolute eosinophil counts rose in 28 patients (70%) before treatment which was normalized in 24 cases (85.71) after treatment [Table 8]. Maximum patients (30) were *vata* kapha predominant.

A total number of 26 (65%) patients were completely relieved from the attack, reduction of severity was observed in 10 (25%) cases of asthma and four (10%) patients did not respond to the treatment [Table 9]. This lack of response may be due to the chronicity of the patients. The improved $PEFR$ values in 36 (90%) cases suggest a bronchodilatation effect which increased the vital capacity of lungs. The $PEFR$ values did not increase in the remaining four (10%) cases, which may be due to the development of respiratory infection and other causes of increased airway obstruction. Breath holding time was normal (>30 sec) in 18 patients (47.5%) and another 10 (25%) improved in BHT . Two patients (5%) had no change in BHT , maybe due to the unstable asthma and reduced oxygen saturation capacity in the alveoli of lungs.

There was a reduction in the absolute eosinophil count in 24 out of 28 cases (85.71%). It clearly indicates that the drug has action over absolute eosinophil count, their mediators and other effector cells responsible in the asthma reaction.

Side-effect

One patient complained of constipation, dryness of mouth and burning sensation in stomach during the treatment. The cause of the side-effect was the *vata prakuti* and old age of the patient.

DISCUSSION

This study is an attempt to examine the clinical response

Table 1: The Ayurvedic pharmacological properties of individual ingredients and formula in *Toto of Padmapatradi yoga*^[21]

| Name of drug with Latin name | Parts used | Gana | Rasa | Guna | Virya | Vipaka | Effect of dose |
|---|-------------------------------|-----------------------------------|----------------------------|------------------------------|-----------------------|---------------|------------------|
| <i>Padmapatra</i> (Puskaramula) <i>Inula recemosa</i> hook | root | Swasahara <i>hikkani-graha</i> | <i>tiktha katu</i> | <i>laghu tikshna</i> | <i>ushna</i> | <i>katu</i> | <i>Kaph vata</i> |
| <i>Bhargi</i> <i>Clerodendrum serratum</i> | root | <i>pippalyadi</i> | <i>tiktha katu</i> | <i>laghu rooksha</i> | <i>ushna</i> | <i>katu</i> | <i>Kaph vata</i> |
| <i>Malaya Vacha</i> <i>Alpinia galanga</i> | <i>Kanda</i> Modified stem | <i>kantya</i> | <i>katu</i> | <i>laghu tikshna rooksha</i> | <i>ushna</i> | <i>katu</i> | <i>Kaph vata</i> |
| <i>Shati</i> <i>Hedychium Spicatum</i> | <i>Kanda</i> Modified stem | Swasahara <i>hikkani-grah</i> | <i>Katu tiktha kashaya</i> | <i>laghu tikshna</i> | <i>ushna</i> | <i>katu</i> | <i>Kaph vata</i> |
| <i>Pippali</i> <i>Piper longum</i> | fruit | <i>pippalyadi</i> | <i>katu</i> | <i>laghu snigda tikshna</i> | <i>Anushna sheeta</i> | <i>madhur</i> | <i>Kaph vata</i> |
| <i>Padmapatradi yoga</i> | - | | <i>Katu tikta</i> | <i>laghu tikshna</i> | <i>ushna</i> | <i>Katu</i> | <i>Kaph vata</i> |

Table 2: The duration of expiratory dyspnoea (*Shwashastvata*)

| Nature of expiratory dyspnoea (<i>Shwashastvata</i>) | No. of patients | Percentage |
|--|-----------------|------------|
| Every day | 10 | 25 |
| Once in two days | 20 | 50 |
| Two to three times per week | 10 | 25 |
| Total | 40 | 100 |

Table 3: The types of cough in 40 treated cases of asthma (*Kapha Sthivana*)

| Types of cough (<i>Kapha Sthivana</i>) | No. of patients | Percentage |
|--|-----------------|------------|
| Mucoid Sputum | 22 | 55 |
| Purulent Sputum | 7 | 17.5 |
| Dry cough | 11 | 27.5 |
| Total | 40 | 100 |

Table 4: The tolerance of the 40 treated cases to physical activities

| Nature of physical activities | No. of patients | Percentage |
|-------------------------------|-----------------|------------|
| Normal physical activities | 15 | 37.5 |
| Reduced physical activities | 20 | 50 |
| Severely reduced activities | 05 | 12.5 |
| Total | 40 | 100 |

Table 5: The nature of attack before and after treatment

| Nature of attack | Before treatment | After treatment |
|------------------|------------------|-----------------|
| Nil | 00 | 26 (65) |
| Mild | 10 | 06 (15) |
| Moderate | 20 | 06 (15) |
| Severe | 10 | 02 (5) |
| Total | 40 | 40 (100) |

of *Padmapatradi yoga* according to the clinical guidelines of Acharya Charaka and global initiation for asthma (1998). The sum total properties of *Padmapatradi yoga* are *tikta katu rasa, laghu and tikna guna* (light and penetrating properties), *ushna virya* (hot potency) and *vata-kaphagna* (decrease vata and kapha dosa). The *gunas* of the drug are *laghu, tikshna* which are antagonistic to the *gunas* of *kapha dosa*, thereby normalizing *kapha dosa*. The *virya* (potency) of this drug

Table 6: Peak expiratory flow rate of 40 treated cases of asthma before and after treatment

| Range of PEFR l/m | Before treatment | After treatment |
|-------------------|------------------|-----------------|
| 50-100 | 10 | 01 |
| 101-150 | 12 | 03 |
| 151-200 | 06 | 04 |
| 201-250 | 05 | 05 |
| 251-300 | 04 | 03 |
| 301-350 | 02 | 12 |
| 351-400 | 01 | 08 |
| > 400 | 00 | 04 |
| Total | 40 | 40 |

Mean PEFR before treatment-174.5±89.6 (Mean ± SD), Mean PEFR after treatment- 288 ±73 (Mean ± SD)

Table 7: Breath holding time of 40 treated cases at different intervals before and treatment

| Range of BHT in sec | Before treatment | After treatment |
|---------------------|------------------|-----------------|
| 0-5 | 16 | 1 |
| 6-10 | 8 | 3 |
| 11-15 | 8 | 2 |
| 16-20 | 5 | 4 |
| 21-25 | 2 | 2 |
| 26-30 | 1 | 10 |
| 31-35 | Nil | 8 |
| 36-40 | Nil | 6 |
| > 40 | Nil | 4 |
| Total | 40 | 40 |

Mean BHT before treatment 13.65± 6 (Mean ± SD), Mean BHT after treatment 22.35± 8.3 (Mean ± SD)

Table 8: Absolute Eosinophil Count of 40 treated cases before and after treatment

| AEC range | Before treatment | After treatment |
|---------------|------------------|-----------------|
| Raised >250 | 28 | 04 |
| Normal 50-250 | 12 | 36 |
| Total | 40 | 40 |

Mean AEC before treatment 270± 152 (Mean ± S.D), Mean AEC after treatment 230± 120 (Mean ± S.D)

is *ushna* (hot), whereas that of *vata* is *sheeta guna* (cold in Character). All the ingredients of *Padmapatradi yoga* have

Table 9: Overall clinical response of 40 treated cases of asthma (*Tamaka Swasa*)

| Clinical response | Number of patients | Percentage |
|-------------------|--------------------|------------|
| Complete relieve | 26 | 65 |
| Marked relieve | 10 | 25 |
| Not responded | 04 | 10 |
| Total | 40 | 100 |

Table 10: Statistical analysis of different parameters before and after treatment

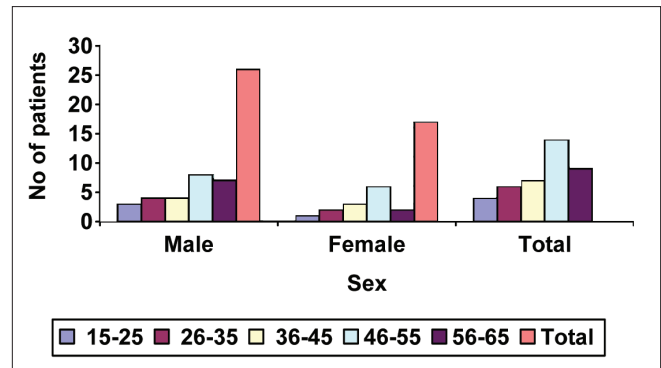
| Parameters | Mean difference | SD | SE | t-value | P value | Remark |
|------------|-----------------|--------|-------|---------|---------|--------|
| PEFR | 113.50 | 66.275 | 14.82 | 7.66 | <0.001 | HS |
| BHT | 10.85 | 6.133 | 1.372 | 7.908 | <0.001 | HS |
| AEC | 40 | 44.72 | 9.999 | 4.00 | <0.001 | HS |

the quality to normalise or suppress the *prakupitha vata dosha* (vitiated vata dosa) by *ushna virya* (hot potency). *Agni mandya* (diminished digestion power) is corrected by *pippali*. *Srotas* vitiated are *pranavaha srotas*, which are corrected by all the drugs as they are *Swasa hara* (reduce expiratory dyspnea) and *kasabara* (decrease cough). *Srotodusty* (The mechanism of manifestation of diseases) is *sanga* (occlusion), which is relieved by the *ushna* (hot) properties of the drug and *swasabara* property. *Adhista* (site of disease) is *amasaya* (upper part of stomach), which is seat of *kapha*, as the ingredient of *Padmapatradi* yoga are *katu*, *tiktha* *rasapradhana*, acting over *kapha dosha* and *amasaya* restoring the normal function of *amasaya* (upper part of Stomach).^[22] By these properties breaking of the pathogenesis (*samprapti nighatana*) takes place.

The cause of the side-effect may be due to the *vata pitta prakuti* and old age of the patient, where *katu*, *tiktha* *rasa* may have further increased the *vata* and manifest constipation. But it is a case of individual response to the treatment.

Bronchial asthma is a chronic inflammatory disorder and mast cell, eosinophils and T-lymphocytes plays an important role.^[23] The ingredients may be collectively effective on airflow obstruction and airway hyper-responsiveness by bronchodilatory, anti-inflammatory and antihistaminic properties.^[24,25] *Inula recemosa* and *Clerodendron serratum* have anti-allergic activities in experimental models. *Hedychium spicatum* have an anti-inflammatory effect. The mechanism of action of *Padmapatradi* yoga is not clear but ingredients of *Padmapatradi* yoga have bronchodilatory, anti-inflammatory and antihistamine activities.

The therapeutic efficacy of this drug is due to multiple blocking and homeostasis of very complex and interdependent cellular and mediator networks supporting and involved in the inflammatory process of asthma. The pharmacological properties like bronchodilatory, anti-

**Figure 1:** Age and sex distribution of the 40 asthma cases studied

inflammatory and antihistaminic may activate the action of *Swasabara* and *kasabara* as described in Ayurveda.

CONCLUSION

Padmapatradi is effective in reducing the severity of attack, and helps in increased PEFR and BHT. Of studied cases and also found statistically highly significant at $P < 0.001$ level [Table 10]. The therapeutic effect of the drug is observed same response irrespective of age and sex in the studied patients. The drug is quite safe and acting as broncho-dilation, anti-inflammatory and anti histaminic.

It is a new therapeutic option in asthma control. Further double-blind placebo-control study in a higher population is recommended.

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