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# A COMPARATIVE CLINICAL STUDY TO EVALUATE THE EFFECT OF PANCHKO-LADI AVLEHA AND TAMAK SWASAHARA AVLEHA IN THE MANAGEMENT OF BALA TAMAK SWASA W.S.R. TO CHILDHOOD ASTHMA

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## ABSTRACT

**Background and objectives:** *Tamak Swasa* is one of the five types of *Swasa Roga*, and it is mentioned as *Yapya Vyadhi. Tamak Swasa* is a disease mainly of *Pranavaha Srotas* and it is a *Kapha-Vata* predominant disorder. The feature of *Tamak Swasa* described in *Ayurveda* is quite comparable with the disease Bronchial Asthma. Childhood asthma is an acute, recurrent and episodic disease. No drug ensures total relief without any side effects and the chance of reoccurrence is relatively high. So, there is a need to have safe, effective easily available treatment modalities to treat this problem. *Ayurveda* has the unique concept of *Vyadhi Kshamatva*, and various measures and recipes are described to achieve it. Considering these facts, a clinical trial will be done to evaluate the efficacy of drugs *Panchkoladi Avleha* and *Tamak Swasahara Avleha*. **Method:** Patients presenting with clinical features of *Tamak Swasa* and between 5 to 16 years of age group irrespective of sex were selected for this study and divided into Group A and Group B with 20 patients in each. Patients in Group-A were managed with *Panchkoladi Avleha* and *Swasahara Avleha* for 4 weeks. **Result:** Data was analysed with appropriate statistical tools. **Interpretation and Conclusion:** *Panchkoladi Avleha* as well as *Tamak Swasahara*. So, these can be used in the management of *Bal Tamak Swasa*.

Keywords: Panchkoladi Avleha, Tamak Swasahara Avleha, Tamak Swasa.

#### INTRODUCTION

Ayurveda is one of the most ancient medical sciences in the world. It is more life and healthoriented. According to Ayurveda, Swasa is a major clinical condition that includes classes and subclasses in it. Tamak Swasa is one of the five types of Swasa Roga, and it is mentioned as Yapya Vyadhi<sup>1</sup>. In classics, it is "Swatantra" Vyadhi has its etiology, pathology, and management. It is a disease condition that is produced by one's own incompatible regimen i.e., Aahara, Vihara, Desha, and Kala. Tamak Swasa is a disease mainly of Pranavaha Srotas and it is a Kapha-Vata predominant disorder<sup>2</sup>. The feature of Tamak Swasa described in Ayurveda is quite comparable with the disease Bronchial Asthma.

Asthma is one of the most common chronic diseases of childhood. It is defined as a chronic inflammatory disorder of the lower airways, characterized by recurrent episodes of variable, reversible air flow obstruction and airway hyper-responsiveness manifested as recurrent wheeze and cough. AHR is the inherent tendency of bronchi to narrow in response to different stimuli, such as allergens, irritants, and infections<sup>3</sup>.

Childhood Asthma is an acute, recurrent and episodic disease. In contemporary medical science, management of Bronchial Asthma is carried out with the usage of bronchodilators, leukotriene antagonists, mast cell stabilizers & corticosteroids. Long-lasting usage produces adverse effects like tachycardia, tremors, hypokalemia, headache, sedation, weight gain, reflex coughing, etc., and also reduces the effectiveness of therapy. No drug ensures total relief without any side effects and the chances of reoccurrence are relatively high. So, there is a need to have a safer and much more effective treatment modality for the condition, which is only possible in Ayurveda. Ayurveda has the unique concept of Vyadhi Kshmatva, and various measures and recipes are described to achieve it. While mentioning the management of Swasa, Acharya's explained that those diets & Drugs having Kaphavataghna, Ushna & Vatanulomana properties are useful in Tamak Swasa<sup>4</sup>. Arundutta further says -

Drugs having *Deepana-Pachana* activities are used for the management of *Tamak Swasa*<sup>5</sup>. Considering all these facts, a clinical trial has been thought to evaluate the efficacy of drugs *Panchkoladi Avleha*<sup>6</sup> and *Tamak Swasahara Avleha*<sup>7</sup> in *Bal Tamak Swasa*. The easily available ingredients of the formulations are found to be *Deepana*, *Amapachak*, *Kaphavatahara*, *Swasahara*, etc. *Tamak Swasa* is a troublesome disease because most *Acharyas* have described it as *Yapya* to treat.

#### MATERIAL AND METHODS:

- Literary source: The available literature on related drugs and disease *Tamak Swasa* vis-a-vis childhood asthma shall be critically reviewed from different *Vedic* scripts, *Upanishads, Ayurvedic* texts, modern *texts, various journals, internet, and retrospective studies done in various institutions.*
- Sample source: The patient will be selected from O.P.D of R.G.G.P.G.A.C Hospital Paprola Distt Kangra (H.P.)

Study design: Comparative clinical study.

- Sample size: 40 patients suffering from *Tamak Swasa* fulfilling the diagnostic and inclusion criteria were selected. Selected patients were divided into two groups.
- Group-A In this group, 20 patients were managed with *Panchkoladi Avleha*.
- Group-B In this group, 20 patients were managed with *Tamak Swasahara Avleha*.

#### Diagnostic criteria

- Clinical assessment was done by various subjective symptoms like:
- Intermittent dry coughing of >7 days (spasmodic coughing- night and early morning)
- Prolonged expiratory wheeze, dyspnoea, chest tightness commonly provoked by physical exertion, and airway irritation.
- 4-5 observed attacks/ year
- Response to broncho-dialators.

#### Inclusion criteria:

- Parents/ guardians of the children willing to participate in the research trial.
- Age group between 5 to 16 years.
- Only mild to moderate stable patients with child-hood asthma were included.
- A positive test of reversibility in oxygen saturation and PEFR in children.

#### **Exclusion criteria:**

- Patients/ parents of the patients are not willing to participate in the trial.
- Patients having severe childhood asthma/ status asthmaticus condition.
- The patient presents systemic illnesses like pneumonitis, pleural effusion, pulmonary T.B., etc.
- Children with congenital anomalies.
- Patients with PEFR <50%.
- Patient on prolonged (>6 weeks) medication with corticosteroids, bronchodilators, mast cell stabilizers, anticholinergics, etc.

#### Study period: 4 weeks, Follow up: 4 weeks

**Doses:** 6- 8years = 2 g tid

9-11 years = 3 g tid

12-16 years = 4 g tid

### Assessment criteria: Subjective criteria of assessment

- Coughing
- Wheezing
- Dyspnoea
- Use of accessory muscles
- Sleep disturbance
- Restlessness
- Nasal discharge

#### **Objective criteria of assessment**

- Respiration rate
- PEFR
- Sp O<sub>2</sub>

#### **Assessment of Improvement:**

The overall effect of therapy is further defined as-

- 100 % improvement in all parameters - Complete remission
- 75%-99% or more improvement in all parameters - Marked relief
- 50%-74% or more improvement in all parameters - Moderate relief
- 25%-49% or more improvement in all parameters - Mild relief
- Less than 25% improvement in the parameters - No relief

## **RESULTS:**

#### Table 01: Comparative results of Group A and Group B

Symptoms	% Relief with 'P' value				
	Group A		Group B		
Coughing	61.54%	< 0.001	55.26%	< 0.001	
Wheezing	65.6%	< 0.001	61.77%	< 0.001	
Dyspnoea	73.07%	< 0.001	68.96%	< 0.001	
Use of accessory muscles	82.60%	< 0.001	90.48%	< 0.001	
Sleep disturbance	65.62%	< 0.001	56.75%	< 0.001	
Restlessness	73.07%	< 0.001	86.36%	< 0.001	
Nasal discharge	90%	< 0.001	80%	< 0.001	
Respiration Rate	47.22%	< 0.001	36.57%	< 0.001	
PEFR	23.52%	< 0.05	23.52%	< 0.05	
SpO2	77.78%	< 0.001	75%	< 0.001	
AEC	28.28%	< 0.001	26.86%	< 0.001	

The results of two drugs were evaluated on the basis of criteria established for assessment of the Overall percentage improvement of each patient was calculated by the following formula: BT-AT/BT\*100

Effects	Group A		Group B	Group B	
	No. of Patients	%age	No. of Patients	%age	
Complete Remission	00	00	00	00%	
Markedly Improved	05	25%	02	10%	
Moderately improved	14	70%	17	85%	
Mildly Improved	01	05%	01	05%	
No improvement	00	00	00	00	

Table 02: Overall percentage improvement

#### DISCUSSION

#### Discussion related to demographic data

**Age:** The patients were classified into 3 age groups. The first group of age 5-8 years, 2nd group was 9-11 years, and 3rd group ranged from 12-16 years. There is no relationship between age and *Tamak Swasa* mentioned in our classical literature.

The age-wise distribution shows that the maximum number of patients were found in between 5-8 years age group 55% (22), followed by 45% (18) in between 9-11 years and 12-16 years age group. The data shows that the onset is common in young children. Since the Tamak Swasa is a Kapha - Vata predominant disease, its incidence should be witnessed more either during the Balyaavastha, which is the normal time of Kapha dominance, or the Vriddhavastha which is the normal time of Vata dominance. Gender: Gender-wise distribution shows that maximum patients i.e., 60 % (24) were males and 40% (16) were females. (Table No. 3) Male predominance - the male-to-female ratio is 2:1 owing to the relatively small airways with which they are born and inherited as an autosomal dominant trait. It is broadly established that allergy in early life and male infants and children is more prevalent.

**Father's education:** Asthma management and control of exacerbation depend largely on the care taken by the parents to provide an adequate allergy-free atmosphere to the kids. Thus, a parental education status survey was done among the registered patients. Maximum no. of parents i.e., 37.5% (22) graduated and only 7.5% (03) were having primary education.

**Socio-Economic status:** Living conditions play an important role in Asthma as environmental factors

are etiologically significant. Socio-Economic status also has importance in providing hygienic living conditions to children. The majority of our patients in this study were from middle-class families 65% (26), 25% (10) were from the lower class & remaining 10% (04) were from the upper class.

**Habitat:** The habitat profile of the registered patients reveals that the maximum number i.e., 85% (34) were from rural areas while 15% (06) patients were from an urban area, as the study was conducted in a rural area.

**Religion:** Religion-wise distribution of patients shows that all the patients i.e., 100% (40) were of hindu religion. The higher frequency of hindu children may be due to the predominance of the hindu community in the study area.

**Hereditary influence:** In the present study maximum number of patients 87.5% (35) had a positive family history either from the maternal or paternal side. It supports the genetic contribution<sup>4</sup> in the development of childhood asthma.

**Risk factors:** The present study reveals that genetic susceptibility 87.5% (35), pet exposure 50% (20), and use of antibiotics in early life 32.5% (13) were major risk factors in patients with bronchial asthma followed by poor ventilation, passive smoking, soft toys, mites, carpets, and early weaning.

The above observations are very well supporting the prior studies. Parental cigarette smoking has been shown to increase the likelihood of asthma. The more cigarettes the mother smoked, the greater the risk of asthma.

**Birth history:** The child born by cesarean section has more risk of asthma as compared to normal vaginal birth. It may be due to modified bacterial exposure during cesarean section<sup>6</sup> compared with vaginal birth that further modified the immune system.

In the present study, 67.5% (27) of patients were having a history of normal vaginal delivery, while 30% (12) of children were delivered by LSCS. Only 2.5% (01) were born by using forceps.

**Birth weight:** Low birth weight babies are prone to develop malnutrition and recurrent infections in later life. The present study showed that 80% (32) patients were having a history of normal birth weight while only 20% (08) were having a history of low birth weight.

**Immunization status:** During the study, it was observed that 100% (40) of patients had received all vaccinations at the proper age because of social awareness and availability of facilities at govt. hospitals in the state.

**Diet:** The majority of the patients were consuming vegetarian food, figuring 72.5% (29) and only 27.5% (11) patients were consuming non-vegetarian food along with vegetarian food, in the present study.

**Pets:** Present study shows that 50% (20) patients were having pets in their houses. This supports the fact that pets are one of the triggering factors for bronchial asthma.

**Aggravating factors:** In the present study aggravating factors for most of the patients were cold air or cold season and smoke i.e., 45% (18) followed by seasonal changes in 37.5% (15) patients; dust and pollens and cloudy weather in 30% (12); cold drinks and mental stress were found in 25% (10) and 12.5% (05) patients respectively.

**Previous history of infectious diseases:** History of infectious diseases revealed that the presence of Recurrent Upper Respiratory Tract Infections was found in 87.5% (35) of patients in the present study. Pneumonia in 37.5% (15) patients, constipation in 20% (08), whereas anaemia and jaundice were reported in 17.5% (07) and 10% (04) patients respectively. These infections may be a cause for the use of antibiotics in early life, a proven cause of respiratory allergic disorders<sup>7</sup>. The precipitating factor for an asthma attack in 40% of children is viral URTI<sup>8</sup>.

Koshtha: Koshtha indicates the status of digestive metabolism. Hence an assessment of Koshtha is important in analyzing the state of health and disease. Vibandha is supposed to be classically a Nidanar-thakara Roga in Tamak Swasa. In the present study, 57.5% (23) patients had Madhyama Koshtha followed by 30% (12) of patients having Krura Koshtha, and only 12.5% (05) patients were having Mridu Koshtha.

**Prakrti:** Proper *Prakrti* analysis is difficult in children because of '*Sarva Dhatu Asampoornata*'. Still, an attempt has been made to analyze the *Prakrti* on the basis of current behavior, physical features, and other physical characters. *Prakrti*-wise analysis of the patients in the study shows a predominance of *Kapha-Vata Prakrti* in 60 % (24) patients while 27.5% (11) were having *Pitta-Kapha Prakrti* and 12.5% (05) were having *Vata Pitta Prakrti*.

As evident from the etiopathogenesis of *Tamak Swasa*, it is a *Kapha-Vata Pradhan* disease, therefore is more likely to attack the individual with *Kapha-Vata Prakriti*, also the severity will be more in these individuals. This observation suggests that *Kapha-Vata Prakriti* is more prone to bronchial asthma in children.

*Nidra*: In the present study it was seen that 92.5% (37) patients were having disturbed sleep and only 7.5% (03) had sound sleep. This may be due to nocturnal coughing and other signs & symptoms of asthma.

#### Discussion regarding the effect of therapy:

**Effect on Coughing:** The mean score of coughing in group A was 1.950 before treatment which was reduced to 0.750 after treatment with 61.54% relief. In group B, the mean score of coughing was 1.900 before treatment which was reduced to 0.850 after treatment with 55.26 % relief. Both the results were statistically highly significant (P<0.001).

Statistically, both the groups showed highly significant relief and there was no statistically significant difference between BT and AT scoring of the two groups (p>0.05). Though Group A showed 6.28% more relief than group B. Improvement in coughing can be attributed due to the pacification of *Vata & Kapha Dosha*, and the removal of the obstructing *Kapha* from the *Pranavaha Srotos* due to the anti-tussive and mucolytic properties of trial drugs.

**Effect on Wheezing:** Before treatment, the mean score of wheezing in group A was 1.60 which was reduced to 0.550 after treatment with 65.6% relief. The mean score of wheezing in group B was 1.700 before treatment which was reduced to 0.650 after treatment with 61.77% relief. Both the results were statistically highly significant (P<0.001).

Statistically, both the groups showed highly significant relief and there was no statistically significant difference between BT and AT scoring of the two groups (p>0.05). Though Group A showed 3.83% more relief than group B.

The effect on wheezing may be due to relieving obstruction caused by *Sama Kapha* and normalizing *Pranavayu*.

**Effect on Dyspnoea**: In group A the mean score of dyspnoea was 1.300 before treatment which was reduced to 0.350 after treatment with 73.07% relief. The mean score of dyspnoeas in group B was 1.450 before treatment which was reduced to 0.400 after treatment with 68.96% relief. Both the results were statistically highly significant (P<0.001).

The Inter-group comparison over dyspnoea was statistically insignificant (p>0.05). Though Group A showed 4.11% more relief than Group B.

**Effect on Use of Accessory muscle:** The mean score obtained before treatment in group A and group B was 1.150 and 1.050 respectively, which was reduced to 0.200 after treatment with 82.60% relief in group A and 0.1000 with 90.48% relief in group B. Both the results were statistically highly significant (P<0.001).

The Inter-group comparison over the use of Accessory muscle was statistically insignificant. Though Group B showed 7.88% more relief than Group A.

**Effect on Sleep Difference-** In group A the mean score of sleep disturbance was 1.600 before treatment which was reduced to 0.550 after treatment with 65.62% relief. The mean score of sleep disturbance in group B was 1.850 before treatment which was re-

duced to 0.800 after treatment with 56.75 % relief. Both the results were statistically highly significant (P < 0.001).

There was no statistically significant difference between BT and AT scoring of the two groups (p>0.05). Though Group A showed 8.87% more relief than group B.

The improvement in sleep is consequent to the relief in dyspnoea, cough, and wheezing due to the activity of trial drugs however the trial drugs do not possess sedative action.

**Effect on Restlessness:** The mean score obtained before treatment in group A and group B was 1.300 and 1.100 respectively, which was reduced to 0.350 after treatment with 73.07% relief in group A and 0.150 with 86.36% relief in group B. The result was statistically highly significant (P<0.001).

There was no statistically significant difference between BT and AT scoring of the two groups (p>0.05). Though Group B showed 13.29 % more relief than Group A.

The effect may be due to relieving obstruction caused by *Sama Kapha* and normalizing *Pranavayu*.

**Effect on Nasal Discharge**: The mean score obtained before treatment in group A and group B was 1.000 and 1.000 respectively, which was reduced to 0.1000 after treatment with 90% relief in group A and 0.200 with 80% relief in group B. Both the results were statistically highly significant (P<0.001).

Statistically in inter-group comparison, the result was insignificant (p>0.05). Though Group A showed 10% more relief than Group B.

The effect may be due to relieving obstruction of the airway and equal distribution of Oxygen along with the increasing effect on hemoglobin.

Effect of therapy on Respiration Rate: The mean score obtained before treatment in group A and group B was 1.800 and 1.750 respectively, which was reduced to 0.950 after treatment with 47.22% relief in group A and 0.950 with 36.57% relief in group B. The result was statistically highly significant (P<0.001).

But the intergroup difference was insignificant statistically (p>0.05). Though Group A showed 10.65% more relief than Group B.

**Effect on PEFR:** The mean score obtained before treatment in both group A and group B was 0.850, which was reduced to 0.650 after treatment with 23.52% relief in both group A and group B. Both the results were statistically significant (P<0.05).

The improvement in PEFR indicates that the trial therapy is capable of modifying the existing airflow limitations caused by obstruction due to *Sama Kapha* in these patients.

**Effect on Oxygen saturation:** The mean score obtained before treatment in group A and group B was 0.900 and 0.800 respectively, which was reduced to 0.200 after treatment with 77.78% relief in group A and 0.200 with 75% relief in group B. Both the results were statistically highly significant (P<0.001).

The Inter-group difference was statistically insignificant (p>0.05). Though Group A showed 2.78% more relief than Group B.

The improvement may be due to relieving obstruction of the airway and equal distribution of Oxygen.

**Effect on AEC:** In group A the score of AEC was 460.500 before treatment which was reduced to 330.250 after treatment with 28.28 % relief. The score of AEC in group B was 464.600 before treatment which was reduced to 339.800 after treatment with 26.86% relief. Both the results were statistically highly significant (P<0.001).

Eosinophils are the key cells for the inflammatory response through their capacity to secrete a wide range of mediators on the airways, resulting in bronchoconstriction. So, the decreased eosinophil count suggests reducing inflammation and relieving bronchoconstriction after the therapy.

#### Probable mode of action of Panchkoladi Avleha:

The drug *Panchkoladi Avleha* consists of many ingredients which excellently balance each other in *Rasa-Panchaka* and enhance the *Vatakaphahara*, *Deepana*, *Pachana*, and *Vatanulomana* properties.

Vata-Kaphahara property of most of the content:
Panchkola, Brihati, Kantkari, Bharangi acts on the

main *Dosha* which contributes to the *Samprapti* viz. *Vata* and *Kapha*.

➤ The main factor in this disease as in many other diseases is Ama and the Deepana- Pachana properties of Panchkola, Brihati, Kantkari, Bharangi digest Ama.

Shothahara Karma of Bharangi, Shunthi, Pippali, and Kantkari will neutralize the Srotorodha in Pranavaha Srotas due to Shotha created by Sama Vata.

> Vatanulomana property Pippali, Pippalimula, Shunthi, and Bharangi maintain the normal flow of Vata.

➤ Madhu has good Kaphahara action and Yogavahi property.

➤ The Ushna Veerya-neutralises the Doshik pathogenesis.

Probable mode of action of *Tamak Swasahara* Avleha:

The drug *Tamak Swasahara Avleha* consists of many ingredients which excellently balance each other in *Rasa Panchaka* and enhance the *Vata Kaphahara*, *Deepana & Paachna* properties.

Vata-Kaphahara property of most of the content alleviates both Vata and Kapha, which are the main Dosha in the pathogenesis.

➤ The main factor in this disease as in many other diseases is Ama and the Deepana-Pachana properties of Pippali, Ghrita, Guda, and Maricha digest Ama.

Shothhara Karma of maximum drugs will neutralize the Srotorodha in Pranavaha Srotas due to Shotha created by Sama Vata.

> The Ushna Veerya-neutralizes the Doshik pathogenesis.

## CONCLUSION

The following conclusion can be drawn from the present study:

- The increasing prevalence of Childhood Asthma is a global issue of concern due to associated long-term compromises in the quality of life.
- Bronchial asthma mentioned in Modern Medicine closely resembles *Tamak Swasa*.

- Child-hood asthma is an important cause of morbidity, school absentees, and frequent visits to pediatricians, clinics, or hospitals.
- *Tamak Swasa* is a *Kapha-Vata Pradhan* disease involving *Pranavaha Srotas* with some *Dushti* of *Annavaha* and *Udakavaha Srotas*.
- The etiological factors mentioned in the GINA guidelines are also similar to the *Ayurvedic Ni-dana* concepts. The host factors mentioned are nothing but the *Dosha-Dushya Sammurcchana* in *Ayurvedic* concepts and the environmental factors are the *Aaharaja- Viharaja Nidana* in classics.
- In both *Ayurveda* and modern management, the primary prevention (*Nidanaparivarjana*) strategy has been given priority.
- The patients were strictly advised to avoid the etiological and aggravating factors.
- The statistical significance of the effect of the trial drugs *Panchkoladi Avleha* and *Tamak Swasahara Avleha* was analyzed separately in all symptoms using paired t-tests.
- Trial drugs are effective in relieving the signs and symptoms of *Tamak Swasa*.
- No adverse effects of the trial drugs were observed during the study period.

The sample size in the study was small so the further extensive study is needed to authenticate the result of the present study.

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