

# A Comparative Clinical Study to evaluate the effect of Vasadi syrup and Satyadi syrup in the management of Tamaka swasa w.s.r. to Childhood Asthma

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## ABSTRACT

**Purpose:**Respiration is the evident feature of life which is carried out by *Prana vayu*. It is a sign of consciousness, provides enthusiasm to human beings.This sole sign of life is affected in this disease *Tamaka swasa*, causing an impendent to the Respiratory function. Public attention in the world recently focuses on asthma because of its rapidly increasing prevalence. Irrespective of the application of advances in modern medicine as well as age old practice of traditional medicines; 100 to 150 million children around the globe suffer from this non-communicable respiratory disease.The international study of asthma and allergy in childhood (ISAAC) estimated asthma prevalence in India to be 6.2%-6.8% in 6-7 years old and 6.4%-6.7% in 12-16 years with more male affected than female. It is chronic disease of *paranvaha srotas*, in which vitiation of *kapha&vata dosha* mainly and origin in *pitta sthana*.Tamaka swasa is characterized by dyspnoea (*swasakrichrata*), chest tightness (*urashula*), wheeze (*Gurgaruktvamhm*) and cough (*kasa*). The paroxysm attack results in handicapped day & sleepless nights, thus disturbing a normal life style of the child. Childhood asthma is responsible for school absenteeism, restricted activities, social, economic & psychological impact on the family.Even though *Tamaka swasa* is considered as *Yapya vyadhi* but it is curable in its initial phase. In today's scenario we have many anti-asthmatic drugs which can effectively control the various paroxysm attack of asthma but fail to control many adverse effects. Many studies need to be carried out in this perspective to find out a better remedy. Also low-cost asthma management programmers should be developed to ensure asthma care is available and affordable for all socio-economic sectors within the population. Considering all these aspects, the present study has been designed to evaluate the efficacy of two *Ayurvedic* formulations. The formulation Vasadi Syrupand Satyadi Syrup have been selected owing its *Vata-Kaphahara, Swasahara, Rasayanaproperties*.

**Method:**Symptomatology related to *Bala Tamaka swasa*, methods of diagnosis, inclusion and exclusion criteria of the patients will be adopted. Essential investigations will be carried out to confirm the diagnosis. A minimum sample of 30 patients in both groups will be assessed during the trial for 30 days with follow up of 15 days. Selected patients will be divided in to two groups.Group A- 15 patients and Group B- 15 patients. The patients will be selected from the OPD of R.G.G.P.G.A.C.Hospital Paprola; Distt. Kangra.(H.P.) 176115.

**Result:** Both the drugs having an appreciable result in the management of *Bala Tamaka swasa* symptoms and significant changes in investigations.

**Conclusion:** *Tamaka swasa* can be efficiently and effectively managed with *Vasadi syrup* and *Satyadi syrup*,the complication is prevented.

**Keywords-***Tamaka swasa, Bronchoial Asthma, Vasadi Syrup, Satyadi Syrup, rasayana*

## INTRODUCTION

‘Search for Medicine That Cures!’ is an everlasting process in the history of mankind.’

Respiration is the evident feature of life which is carried out by *Prana vayu*<sup>1</sup>. It is a sign of consciousness, provides enthusiasm to human beings. This sole sign of life is affected in this disease *Tamaka swasa* [congruent to bronchial asthma], causing an impendent to the Respiratory function.

Disease asthma has been described since antiquity<sup>2</sup>. Public attention in the world recently focuses on asthma because of its rapidly increasing prevalence, affecting up to rural: urban :: 1:4 urban children mainly<sup>3</sup>. Irrespective of the application of advances in modern medicine as well as age old practice of traditional medicines; 100 to 150 million children around the globe suffer from this non-communicable respiratory disease.

Asthma is increasing with growing urbanization; there may be an additional 100 million children with asthma by 2025. The reported prevalence of asthma in children with an estimate of 1-18%. The international study of asthma and allergy in childhood (ISAAC) estimated asthma prevalence in India to be 6.2%-6.8% in 6-7 years old and 6.4%-6.7% in 12-16 years with more male affected than female. It is the third – ranking cause of hospitalization among those younger than 15 years<sup>4</sup>.

Both *Ayurveda* and Modern medical science agree regarding the *nidana* of the disease as Host factors (*Nija Hetus - Doshadushti and Ama*) and Environmental factors (*Agantuja Hetu's – Raja, Dhuma, Pragvata, etc*)<sup>5</sup>.

In *Charaka samhita*, *Tamaka swasa* is included as one of the variety among five types of *swasa*. It is chronic disease of *paranvaha srotas*, in which vitiation of *kapha&vata dosha* mainly and origin in *pitta sthana*<sup>6</sup>. *Tamaka swasa* is characterized by dyspnoea (*swasakrichrata*), chest tightness (*urashula*), wheeze (*Gurgaruktvamhm*) and cough (*kasa*)<sup>7</sup>. The paroxysm attack results in handicapped day & sleepless nights, thus disturbing a normal life style of the child. Childhood asthma is responsible for school absenteeism, restricted activities, social, economic & psychological impact on the family.

Difficulty in breathing is due to the result of obstructed *pranavaha srotas*. The normal breathing is the function of *prakrita vata*, when it is aggravated due obstruction it produces abnormal breathing. Even though *Tamaka swasa* is considered as *Yapya vyadhi*<sup>8</sup> but it is curable in its initial phase.

In today's scenario we have many anti-asthmatic drugs which can effectively control the various paroxysm attack of asthma but fail to control many adverse effects. **Therefore the management criteria should be designed not only to cure the symptoms but also to improve the quality of life with a better immunity.** Many studies need to be carried out in this perspective to find out a better remedy.

Also low-cost asthma management programmers should be developed to ensure asthma care is available and affordable for all socio-economic sectors within the population.

Considering all these aspects, the present study has been designed to evaluate the efficacy of two *Ayurvedic* formulations. The formulation Vasadi Syrup<sup>9</sup> and Satyadi Syrup<sup>10</sup> have been selected owing its *Vata-Kaphahara, Swasahara, Rasayana* and immune-modulator properties. The formulation possess less number of ingredients, easily available, cost effective & can be easily administered.

#### Aims and objectives:

- 1) To review the ayurvedic and modern literature related to Tamaka swasa.
- 2) To compare the effect of Vasadi syrup and Satyadi syrup in the management of Tamaka swasa in children.
- 3) To established a safe and cost effective medicine for the treatment of Bala Tamaka swasa.
- 4) To study the associated effect of trial drugs, if any.

#### ETHICAL CLEARANCE- No. Ay/IEC/2015/1083

The proposed clinical study was presented in the form of a synopsis in front of the Institutional Ethics Committee. The clinical trial was started after the approval from the Chairman of Ethics committee.

**Plan of Study:** Research work will be planned in the following way:

- 1) Conceptual study
- 2) Clinical study

**Conceptual study:** Literature related to *Bala Tamaka swasa* vis-à-vis Childhood asthma as well as literature related to trial drugs will be critically reviewed.

**Clinical Study:** This will be the main part of proposed research work. Symptomatology related to *Bala Tamaka swasa*, methods of diagnosis, inclusion and exclusion criteria of the patients will be adopted. Essential investigations will be carried out to confirm the diagnosis. A minimum sample of 30 patients in both groups will be assessed during the trial. The patients will be select ed from the OPD of R.G.G.P.G.A.C.Hospital Paprola; Distt. Kangra.(H.P.) 176115.

#### Research protocol:

##### Consent of the parents/guardians of the patient

Written and informed consent of the parents/ guardians of the patient will be taken before the trial.

**Grouping of patients:** Selected patients will be divided in to two groups.

Group A- 15 patients

Group B- 15 patients.

Group A

Group B



Vasadi syrup



Satyadi syrup

The Drugs will be prepared in the college Charak Pharmacy under the supervision of deptt. Of Rasa-shastra and Bhaishajya-kalpana.

**Trial Drug:**

The present clinical study is planned to evaluate and compare the effect of Vasadi syrup and Satyadi syrup i.e. *Vasadi syrup*<sup>9</sup>

**Table no - 1**

Sr. No.	Name	Botanical name	Family	Part used
1	Vasa	<i>Adhatoda vasica</i> Nees.	Acanthaceae	Leaves
2	Shunti	<i>Zingiber officinalis</i> Rose.	Zingiberaceae	Rhizome
3	Kantkari	<i>Solaunum surattense</i> Burm. F.	Solanaceae	Whole plant
4	Guduchi	<i>Tinospora cordifolia</i> Wild.	Menispermaceae	Stem

*Satyadi Syrup*<sup>10</sup>

**Table no - 2**

Sr. No	Name	Botanical name	Family	Part used	Qty.
1	Sati	<i>Hedychium spicatum</i> Buchhlam	Zinzebraceae	Rhizome	1 part
2	Tamalki	<i>Phyllanthus urinaria</i> Hook. F. non Linn.	Euphorbiaceae	Whole plant	1 part
3	Sugandhbala	<i>Valeriana jatamansi</i> D.C.	Valerianaceae	Root	1 part
4.	Bharngi	<i>Cleroderum seratum</i> Linn.	Verbenaceae	Root	1 part
5	Choraka (Chanda)	<i>Angelica glauca</i> Linn.	Umbliferae	Root	1 part
6	Puskarmoola	<i>Inula racemosa</i> Hook. F.	Compositae	Root	1 part
7.	Sharkara				8 part

❖ The raw drugs were taken from the M/S Nihal

Chand and Wazir Chand due to the unavailability of these drugs in Charaka pharmacy Paprola and Jogindernagar pharmacy. The *Yavkut Churna* of these drugs was prepared in Charaka Pharmacy Paprola & was tested at Govt. Drug Testing Lab, Jogindernagar, Distt. Mandi.

**Syrup preparation**<sup>11</sup>

Patients were advised to take 40g of crude drug ( *Yavkut Churna*) in a pot, add 320ml of water and boil it upto 1/4<sup>th</sup> reduction.

- **Dosage of the drug**
- 03-07 years of age - 20 ml / day in three divided doses
- 07-10 years of age - 30 ml / day in three divided doses
- 11-15years of age - 40 ml / day in three divided doses

**STUDY SCHEDULES**

- Screening
- Enrollment

c. Follow up

**a. Screening**

The patients attending the OPD/IPD department with symptoms and signs of *Bala Tamaka Swasa* were considered for inclusion in the study.

**Consent** – Written and informed consent of patients was taken before inclusion in the trial.

**b. Enrollment**

**Selection of patients**

Patients were selected from the OPD/IPD of RGGPG Ayurvedic College & Hospital, Paprola (Kangra) randomly fulfilling the criteria of diagnosis.

**Inclusion criteria:**

- Parents/ Guardian of the children willing to participate in the research trial.
- Age group between 3 to 16years.
- Only mild to moderate stable patients of childhood asthma will be included.

**Exclusion criteria:**

- Patients /parents of the patients not willing to participate in the trial.
- Patient having severe childhood asthma/ Status asthmatic’s condition.
- Patient presenting systemic illness like pneumonitis, pleural effusion, pulmonary T.B. etc.
- Children with congenital anomalies.
- Patient with PEFr < 50% and FEV1 <50%
- Patient on prolonged (>6 week) medication with corticosteroids, bronchodilator’s, mast cell stabilizers, anti cholinergics etc.

**Assessment criteria:**

Patient will be thoroughly assessed on the basis of detailed medical history, family history, H/o eczema/atopic dermatitis and exposure to specific triggers by interview followed by clinical assessment. Clinical assessment will be done by various subjective symptoms like:

- Intermittent dry coughing of >7 days (spasmodic coughing -nocturnal and early morning).
- Prolonged expiratory wheeze, dyspnea , chest tightness commonly provoked by physical exertion & airway irritation.
- 4-5 observed attacks/year
- Response to bronchodilator’s

**Clinical assessment by objective parameters like:**

- Oxygen saturation- in younger children less than 6 years
- Peak expiratory flow rate
- FEV1:FCV

Scoring system will be adopted to assess improvement in various subjective/objective parameters.

**Follow up** : Each fortnight and after completion of trial.

**Laboratory Investigation:** The laboratory Investigations will be done before and after the trial.

- Blood – Hb gm% ,TLC,DLC, ESR , AEC
- PEFr - Above the age of 6 years.
- Oxygen saturation- below the age of 6 years.

Assessment was done on the basis of the subjective and objective parameters before & after treatment. Assessment of subjective parameter (clinical features)and parameters depending upon severity was done as four point scale.

• <b>Scoring</b>	
• Nil	0
• Mild	1
• Moderate	2
• Severe	3
• <b>Kasa (COUGH)</b>	
• No cough	0
• Intermittent cough	1
• Persistent coughing provoked with exercise	2
• Continuous coughing with chest pain	3
• <b>Gurgaruktvamhm(WHEEZING)</b>	
• None	0
• Terminal expiration ( <b>Mild wheezing</b> )	1
• Entire expiration with stethoscope ( <b>Moderate Wheezing</b> )	2

- During inspiration and expiration without stethoscope(**Severe Wheezing**) 3
- **Swasakrichrata (DYSPONEA)**
- No breathlessness 0
- Breathlessness provoked with moderate exercise 1
- Breathlessness provoked with mild exercise 2
- Continues breathlessness 3
- **Use of accessory muscles (Sternomastoid activity)**
- No apparent activity 0
- Questionable increased activity (mild retraction) 1
- Apparent increased activity (moderate retraction) 2
- Maximal activity including nasal flaring (severe retraction) 3
- **Anidra (Sleep disturbance)**
- No sleep disturbance 0
- Little interruption with coughing 1
- Moderate inturruption with exacerbation 2
- Frequent sleep disturbance 3
- **Arati (Restlessness)**
- No difficulty in speaking 0
- Mild difficulty in sleeping 1
- Moderate difficulty in sleeping 2
- Severe difficulty in sleeping 3
- **Nasa srava (Nasal discharge )**
- No discharge 0
- Running nose without visible fluid 1
- Running nose with visible fluid 2
- Continuous discharge with copious fluid 3
- **Vaktravairasya (Colour of face)**
- Pink 0
- Pale 1
- Ashen gray 2
- cyanotic(bluish) 3

**Objective Criteria**

**Respiration rate**

Scoring Children below 6yr

- less than 30/min 0
- 31-45/min 1
- 46-60/min 2
- . >60/min 3
- Children >6yr
- . <20/min 0
- . 21-35/min 1
- . 36-50/min 2
- . >50/min 3
- PEFR**
- more than 90% 0
- . 70-90% 1
- . 50-70% 2
- . less than 50% 3
- Sp O2**
- >95% 0
- 76-95% 1
- 51-75% 2
- . <50% 3

**FINAL ASSESSMENT OF RESULTS**

Patients were assessed before and after the treatment for improvement in symptoms on the basis of above said scoring pattern and percentage improvement was calculated.

**Statistical Analysis:**

The obtained data was analyzed statistically and expressed in terms of mean score before treatment (BT), after treatment (AT), difference of mean (BT – AT), standard deviation (SD) and standard error (SE).

Overall percentage improvement of each patient was calculated by the following formula:

$$\frac{\text{Total BT} - \text{Total AT}}{\text{Total BT}} \times 100$$

Students paired ‘t’ test was applied at  $p > 0.05$ ,  $p < 0.05$ ,  $p < 0.01$ , and  $p < 0.001$ , to observe significance of results obtained after treatment. The results were considered significant or insignificant depending upon the value of p.

- Extremely significant -  $p < 0.0001$
- Highly significant -  $p < 0.001$
- Moderately significant -  $p < 0.01$
- Significant -  $p < 0.05$
- Insignificant -  $p > 0.05$

**OBSERVATIONS & RESULTS**

In the present study, 30 patients were studied. These patients were treated in two groups. 15 patients in Group-I and 15 patients in Group-II were registered. Hence the demographic data is presented according to 30 cases.

**RESULT-** Observation and results obtained were statistically analyzed by using student paired ‘t’ test and unpaired ‘t’ test and presented in the form of thesis.

In the present study, total 30 patients of Tamaka Shvasa were registered. All the patients completed the course of the treatment nobody left the treatment. The Vital data pertaining to 30 patients of Tamaka Shvasa is being described below.

**Age wise distribution** shows that the maximum numbers of patients were in age group 3-6 years (30.7%) and also in 7-11 (46%) years while in 12-16 years age group 26.3% are registered .

**Sex:** This Table reveals that maximum number of patients 90% were male whereas only 10% of patients were female.

**Religion:** In the present study majority of the children belonged to Hindu community 96.66% and rest of were i.e. 3.33% from Muslim community.

**Education** Maximum numbers of patients i.e. 84% were school going students while 16 % were preschool children.

**Socio-Economic Status:** Living conditions play a role in Asthma were environmental factors are aetiologically significant. Socio Economic status also has importance in providing hygienic living condition to children. Majority of our patients in this study were from Middle Class Families (60%). 10 % were from Upper Middle Class and 30% only were belonging to Lower class family and none of the patients were from creamy layer of the society.

**Habitat** profile of the registered patients reveals that maximum number i.e. 83% were from rural area while 17% patients were from urban area.

**Chronicity** of 7 to 11 yrs was found in maximum patients 74%, 12 to 16yrs was found in 16%, and 3 to 6 yrs was found in 10%.

**Frequency of attack** was not found daily, weekly in 3% fortnightly in 47% and monthly in 50%.

**Place of delivery** indicates the availability of proper perinatal, post-natal and neonatal care and the assessment of health condition of the neonate. In the study, 90% of children were delivered in Hospitals and 10% at home.

**Immunization** The registered patients were properly immunized to their age. Artificial immunization is essential for enhancing the primary immunity of the child.

**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 Vata Pitta Prakrti scoring upto 23%. Pitta Kapha were comparatively less scoring up to 3%. KaphaVata Prakrti were 74 % .

**Sara** Children generally have *Alpa Satwa* and *Avara Sara* due to *Sukumarata* and *Sarva dhatu asampoornata*. Among them also relative variation in Sara can be seen in constitution and strength. 3% of patients of *Tamaka Shvasa* in the present study were weak and had *Avara Sara*. 97% had *Madhyama Sara* and no one was found to have *Pravara Sara*.

**Samhanana:** *Dhatu asampoornata* makes the children poor in *Samhanana* also. Again relative assessment to age has been adopted here. More than half of the total patients showed *Avara Samhanana*, 3%, *Madhyama Samhanana* has been noted in 97% and nobody is having an *Uttama Samhanana*.

**Satwabala** is comparatively very low in kids. On the basis of *Klesha Sahishnuta* and general nature of behavior, the patients in the study were classified into *Pravara*, *Madhya* and *Avara-Satwa*. 57.69% were of *Madhyama Satwa*, 15.38% were *Pravara Satwa* and 26.93% were having *Avara Satwa*.

**Koshtha** indicates the status of digestive metabolism. Hence an assessment of Koshtha is important in analyzing the state of health and disease. *Vibandha* is indicated classically as a *Nidanarthakara roga* in *Tamaka Shvasa*. In the present study 3.35% of patients were having *Mridu Koshtha*, 90% had *Madhyama Koshtha* and 6.62% of patients reported *Krura Koshtha* only.

**Comorbidities** Presence of Recurrent Upper Respiratory Tract Infections was found in 56.6% of patients in the present study. Constipation in 13.3%, Jaundice in 3.3% and Pneumonia in 10%, 16.6% patients were reported Anaemic.

**Family history** Interestingly in the present study except for a minor percentage of 6.7% majority of the patients had a positive family history either from the maternal or paternal side

**Seasonal variations** Asthma is highly influenced by seasonal variations. The entire patients i.e.100%, showed an increase in frequency and intensity of attacks in winter season. 33.85% showed an increase during rainy seasons also.

**EFFECT OF THERAPY:**

Total 30 patients were registered for treatment, all of among them were completed the course of whole treatment. So 15 patients in Group A, 15 Patients in Group B. The Effect of the therapy was assessed in both the groups with common parameters and after a same interval of time. The following results were obtained after the completion of the therapy. The under given syrup enumerate results on comparative basis.

Table no - 2

S.No.	Clinical features	N	Mean score		D (BT - AT)	%age of Relief	SD±	SE±	t	P
			BT	AT						
1	<b>Kasa</b>	15	1.533	0.467	1.067	69.55%	0.884	0.228	4.675	<0.001
2	Gurguratvam	15	1.667	0.533	1.133	60%	0.743	0.192	5.906	<0.01
3	<b>Swasakrichata</b>	12	1.400	0.300	1.1	78%	0.799	0.206	4.183	<0.001
4	Use of accessory muscles	12	1.200	0.200	1.00	60.3%	0.845	0.218	4.583	<0.01
5	<b>Anidra</b>	14	1.467	0.400	1.067	72.7%	0.704	0.182	5.870	<0.001
6	Arati	15	1.467	0.133	1.33	90.9%	0.617	0.159	8.367	<0.01
7	<b>Nasasrava</b>	11	1.267	0.267	1.00	78.9%	0.926	0.239	4.183	<0.001
8	Vakravairasaya	1	0.066	0.00	0.066	1%	0.258	0.066	1	>0.5

- In group A the mean score of Kasa was 1.533 before treatment which was reduced to 0.467 after treatment with 69.55% relief.
- Before treatment the mean score of Gurgaruktvamhm in group A was 1.667 which was reduced to 0.533 after treatment with 68% relief.
- In group A the mean score of swasakrichata was 1.400 before treatment which was reduced to 0.30 after treatment with 78% relief.

- Use of accessory muscles in group A the mean score was 1.200 before treatment which was reduced to 0.200 after treatment with 83.30% relief.
- In group A the mean score of Anidra was 1.467 before treatment which was reduced to 0.40 after treatment with 72.00% relief.
- In group A the mean score of Arati was 1.467 before treatment which was reduced to 0.40 after treatment with 90.9% relief.
- In group A the mean score of Nasasrava was 1.267 before treatment which was reduced to 0.267 after treatment with 78.9% relief.
- In group A the mean score of Vakravairasya was 0.066 before treatment which was reduced to 0.00 after treatment with 1% relief.

Table no - 3

S.No.	Clinical features	N	Mean score		D (BT - AT)	%age of Relief	SD±	SE±	t	P
			BT	AT						
1	<b>Kasa</b>	15	1.667	0.400	1.267	76%	0.704	0.182	6.971	<0.001
2	<b>Gurguratvam</b>	15	1.733	0.600	1.133	65.3%	0.640	0.165	6.859	<0.001
3	Swasakrichata	13	1.400	0.400	1.00	56.4%	0.926	0.239	4.183	<0.01
4	Use of accessroy muscles	10	0.867	0.133	0.733	60%	0.704	0.182	4.036	<0.01
5	<b>Anidra</b>	13	1.200	0.533	0.667	55.5%	0.900	0.232	2.870	<0.01
6	Arati	15	1.400	0.267	1.133	80.9%	0.640	0.165	6.859	<0.001
7	<b>Nasasrava</b>	13	1.267	0.400	0.867	68.4%	0.640	0.165	5.245	<0.001
8	Vakravairasaya	0	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00

- The mean score of *Kasa* in group B was 1.667 before treatment which was reduced to 0.400 after treatment with 76% relief.
- The mean score of *Gurgaruktvamhm* group B was 1.733 before treatment which was reduced to 0.600 after treatment with 65.3% relief.
- The mean score of *Swasakrichta* in group B was 1.400 before treatment which was reduced to 0.40 after treatment with 71.4% relief.
- The mean score of *use of accessory muscles* in group B was 0.867 before treatment which was reduced to 0.133 after treatment with 84% relief.
- The mean score of *Anidra* in group B was 1.20 before treatment which was reduced to 0.53 after treatment with 74.19% relief.
- The mean score of *Arati* in group B was 1.40 before treatment which was reduced to 0.26 after treatment with 80.9% relief.
- The mean score of *Nasasrava* in group B was 1.267 before treatment which was reduced to 0.400 after treatment with 68.4% relief.
- The mean score of *Vaktravairasya* in group B was 00 before treatment which was reduced to 0.00 after treatment with 0.00 relief.



Inter group comparison over criteria of assessment (unpaired t test):

Table no - 4

N		Clinical Features	%age Relief		%age relief Difference	S.D	S.E	t	Re-Marks
Gr.-I	Gr.-II		Gr.- I	Gr.-II					
15	15	Kasa	69.55%	76%	7%	0.704	0.182	6.971	H.S.
15	15	Gurguratvam	60%	65.3%	5%	0.640	0.165	6.859	S
12	13	Swasakrichata	78%	56.4%	18%	0.926	0.239	4.183	S
12	10	Use of accessroy muscles	60.3%	60%	0.3%	0.704	0.182	4.036	S
14	13	Anidra	72.7%	55.5%	7%	0.900	0.232	2.870	S
15	15	Arati	90.9%	80.9%	10%	0.640	0.165	6.859	S
11	13	Nasasrava	78.9%	68.4%	10.2%	0.640	0.165	5.245	H.S.
1	0	Vakravairasaya	1%	0.00	1%	0.00	0.00	0.00	N.S.

OVERALL EFFECT OF THERAPY (SUBJECTIVE CRITERIA)

Table no - 5

Effects	Group A		Group B	
	No. of Patients	%age	No. of Patients	%age
Complete Remission	00	00	00	00
Markedly Improved	06	40%	08	53.3%
Moderately improved	07	46.6%	06	40%
Mildly Improved	02	13.3%	01	6.6%
No improvement	00	00	00	

In Group A (15 patients), marked improvement in 40%, moderate improvement in 46.6%, mild improvement in 13.3% patients were found. While in Group B (15 patients), marked improvement in 53.3%, moderate improvement in 40%, and mild improvement in 6.6%. Thus, in group A maximum number of patients i.e. 46.67% of patients respectively showed moderate improvement and group B maximum number of patients i.e. 53.3% showed marked improvement.

EFFECT OF THERAPY ON THE BASIS OF OBJECTIVE CRITERIA

Table no - 6

S.No.	Clinical features	N	Mean score		D (BT - AT)	%age of Relief	SD±	SE±	t	p
			BT	AT						
1	Respiration rate	15	0.867	0.800	0.066	7.7%	0.458	0.118	0.564	>0.05
2	PEFR	10	1.692	0.846	0.846	50%	0.376	0.104	8.124	<0.01

3	Oxygen Saturation	15	0.800	0.667	0.133	25%	0.352	0.09	1.468	0.164
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- In group A the mean score was 0.867 before treatment which was reduced to 0.800 after treatment with 7.72% relief.
- In group A the mean score of PEFR was 1.692 before treatment which was reduced to 0.84 after treatment with 50.00% relief.
- In group A the mean score was 0.800 before treatment which was reduced to 0.667 after treatment with 25.00% relief.

Table no - 7

S.No.	Clinical features	N	Mean score		D (BT - AT)	%age of Relief	SD±	SE±	t	p
			BT	AT						
1	Respiration rate	15	0.867	0.800	0.066	7%	0.258	0.118	1.000	>0.05
2	PEFR	11	1.846	1.154	0.692	37%	0.480	0.133	5.196	<0.01
3	Oxygen Saturation	11	1.846	1.154	0.692	37%	0.480	0.133	5.196	<0.01

- The mean score of group B was 0.867 before treatment which was reduced to 0.800 after treatment with 7.72% relief.
- The mean score of PEFR in group B was 1.84 before treatment which was reduced to 1.1 after treatment with 37.48% relief.
- The mean score of group B was 0.86 before treatment which was reduced to 0.33 after treatment with 62.4% relief.

Effect of Therapy on Blood Examinations:

Table no - 8

S.No.	Clinical features	N	Mean score		D (BT - AT)	%age of Relief	SD±	SE±	t	p
			BT	AT						
1	Hb gm %	15	12.8	13.2	0.414	4%	1.013	0.261	1.530	>0.05
2	TLC	15	8661.1	8722.2	0.7	7%	3316.2	781.658	0.078	>0.05
3	ESR	15	10.867	5.000	5.867	53.47%	7.791	2.012	2.916	<0.01
4	AEC	15	0.046	0.022	0.024	52%	0.011	0.002	8.290	<0.001

- In Hb% value, mean score before treatment in both A was 12.8 and it was 13.2 respectively after treatment.
- The haematological parameters in group I were within normal limits both before and after the therapy.
- In E.S.R. value, mean score before treatment in both A was 10.86 and 5.00 respectively after treatment.
- In group A the mean score of AEC was 0.046 before treatment which was reduced to 0.022 after treatment with 52.00% relief.

Table no - 9

S.No.	Clinical features	N	Mean score	D (BT - AT)	%age of Relief	SD±	SE±	t	p
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			BT	AT	AT)	Relief				
1	Hb gm %	15	12.8	12.49	0.313	3%	0.806	0.208	1.505	>0.05
2	TLC	15	8083.3	7416.6	1.33	8%	1412.54	332.94	2.002	>0.05
3	ESR	15	14.733	6.800	7.933	53.7%	7.106	1.835	4.324	<0.001
4	AEC	15	0.046	0.030	0.016	34.7%	0.006	0.001	10.4	<0.001

- In Hb% value, mean score before treatment in both A was 12.8 and it was 12.4 respectively after treatment.
- The haematological parameters in group I was within normal limits both before and after the therapy.
- In E.S.R. value, mean score before treatment in group b was 14.7 and 6.80 respectively after treatment with 53.7% relief.
- In group A the mean score of AEC was 0.046 before treatment which was reduced to 0.030 after treatment with 34.00% relief.

## DISCUSSION

*Swasa roga* is classified into five on the basis of severity. *Khsudra shwasa* can be seen as a symptom in many diseases and is self-limiting. *Chhinna*, *Urdhwa* and *Maha shwasa* are the terminal stages and have extremely bad prognosis. Hence in all practical senses, *Tamaka Shwasa*<sup>12</sup> is the main among these five types for management point of view.

*Tamaka Shwasa* is a disease in which *vayu*, is vitiated and blocked by *kapha*, moves upward instead of its normal flow to the *uras*<sup>1</sup>. This is clearly observed in the labored expiration, which becomes an active process in asthmatics instead of the normal passive expiration. The disease is predominantly caused by *Pranavaha sroto dushti*. The classical symptoms of *pranavaha sroto dushti* as described by *Charaka* can be seen as it is in typical cases of Asthma. The airway pathology in Asthma in modern parlance corresponds literally with the *sanga purvaka vimarga gaman* and resultant *Ati-pravrutti* of *Shwasa*<sup>13</sup>. Rarely in Ayurveda literature we can see such explicit and detailed description encompassing the minutest details of pathologic features as in *Tamaka shwasa*. The latest advancement in modern medicine is now revealing objectively the details of these pathological features, which our *Acharyas* had codified centuries ago. Whether it is *Acharya Sharmadhar's* account of *shwasa kriya*<sup>14</sup>, or *Charaka's* explanation of *Shwasa samprapti*, or be it the explanations regarding *Pranavaha sroto dushti*, these accounts reveal in detail the etio-pathogenesis of *Shwasa roga* exactly in the same line as now being understood by Modern Medical researchers.

Generally, in modern medical approach, the focus is primarily on management of diseases and less importance is given to the prophylactic aspect. In Asthma, modern chest medicine specialists emphasize the need of prevention in the control of Asthma. GINA has highlighted the importance of Primary Prevention strategy in their guidelines for Asthma management.

While *Ayurveda* defines *Chikitsa* as *Nidana parivarjanam*, and gives equal importance to the avoidance of Causative factors, Modern medicine lately has come out with 'primary prevention strategies. GINA guideline priorities the avoidance of risk factors over reliever medications<sup>4</sup>. The list of *Aharaja* and *Viharajanidanans* and *Anupashaya* in *Tamaka shwasa prakarana* coincides with the risk factors explained in recent Asthma guidelines almost in its entirety. The classification of etiological factors as Host and Environmental factors by World Asthma Council corresponds to *Ayurvedic* view of *nija hetus* which are *dosha-sroto dushti* and *Aganthuka nidanas* like *raja*, *dhooma* etc<sup>5</sup>. There are striking similarities in the description of mechanism of Asthma and its pathogenesis between modern and *Ayurvedic* concepts. Asthma is described as a disorder of airways characterized by airway inflammation due to hyper responsiveness of airway cells. There is airway obstruction and mucous plug formation leading to airflow limitation causing symptoms of Asthma. *Ayurveda* explains this as *pratiloma gati* of *Vayu* and subsequent obstruction of *Pranavaha srotas* by *udirita kapha*, which loses its natural attributes and becomes condensed in the *srotas*.

*Dalhana* says that the term *Pratiloma gati* emphasises the mechanism of obstruction of the channel by *Kapha* which is the cause of the *Pratiloma gati*. But, this *Kapha* which is *uras*, is infact agitated by the already vitiated *Vata dosha*.

Thus the pathogenesis is initiated by *Pratiloma gati* of *vayu* due to other reasons than the obstruction by *kapha*. These reasons can be the narrowing of airway due to inflammation. The invasion of *Āma* on *Vata* creates *sotha* in *Pranavaha srotas*. The inflammatory response leads to broncho constriction, leading to an initial *Pratiloma gati* of *Vayu* It has to be remembered that this mechanism happens at the stage of *Sthanasamshraya*, before the *vyakti* of the disease. This is the reason why *Pranasyavilomata* is seen as the *Purvarupa* of *Shwasa*. The concept of *pranavaha srotodushiti* and its explanations matches almost in entirety with the pathogenesis, mechanisms and symptoms of Asthma.

In the *samprapti* of *Tamaka shwasa*, *Acharyas* have explained the *dushti* of *prana*, *udaka* and *anna vahini srotamsi*<sup>16</sup>. Practically the signs and symptoms seen in asthma show the *dushti lakshanas* of *Prana* and *Anna vaha srotas*. The disease is described as *Pittasthana samudbhava* by *Charaka* and *Amashaya samudbhava* by *Vagbhata*. *Chakrapani* explains *Pitta stana* as *adho Amashaya*. In all practical aspects, the disease is *vata* predominant with *kapha* as the second *dosha*.

The involvement of Āma in the pathogenesis of disease is very significant as seen above. Thus it can be logically inferred that the disease has *Amashaya samudbhavathwa*. Āma will naturally derange pitta and the *pittastana dushti* thus is an initial step in pathogenesis. The million dollar question of whether *Ama samudpanna* is the initial phenomenon in dosha dushti or whether it is the *dosha dushti* creating Āma is still to be answered.

But in the case of Asthma, it can be seen that derailment of Agni is seen in almost all the patients with few exceptions. By a critical analysis of classics and their commentaries and logical correlation with practical experience it can be said that the Acute exacerbations are due to the direct *dosha dushti* of vata followed by *udeerana* of kapha. *Samata* of vata is an important factor in the initiation of disease. It is practically noticed that the acute exacerbations are mostly due to *vata prakopakara hetus* like *raja*, *dhuma*, refrigerated food which are both *ati sheeta* and *Ruksha*, *ati Vyayama* and *shoka*, *bhaya* etc. which are emotional factors.

#### Drug<sup>10,11</sup>:

Ayurvedic texts have infinite number of herbal combinations for successful treatment of *Tamaka swasa*. In the present research work, ideal drug's *Vasadi* syrup and *Satyadi* syrurp in the management of *Tamaka swasa* was selected prepared in the form of syrup base for clinical trial. The drug in the form of *Churna* is not easily acceptable to the patients of pediatric age group, so it is prepared in the form of sweet syrup base.

Drugs having *Vata Kaphahara*, *Ushna* and *Vatanulomana* properties are prescribed. Hence, drugs which are widely used by ancient scholars were selected for present study and also *Vasadi syrup* and *Satyadi syrurp* which are having *Kaphahara* and *Shvasa-Kasahara* property has been selected. Drugs which are available easily, having low cost and can be used safely are selected and compound preparation in the form of Syrup has been prepared.

Application of *Prakriti Samasamveta* principle reveals dominancy of *Tikta rasa* along with *Madhura*, *Katu*, and *Kashaya Rasa*. *Avaleha* may work as *Rasayana* for the *Pranavaha Srotas* and also shows *Kapha-Vata hara* effect. To assess the efficacy of new remedy *Vasadi syrup* and *Satyadi syrup* scientific clinical study has been designed. This clinical trial is a carefully and ethically designed experiment with an aim to answer precisely framed questions. The drugs in the formulation also have *Deepana*, *Pachana* properties which control the initial *Ama* formation which is very important in preventing the disease. The *Samana* of *Vata* will be neutralised by these action. Once this is done the *Vata-Kaphahara* action of the drug specify both the causative *doshas* relieving the symptoms. The various published database described the Anti-inflammatory, Anti allergic, Immunomodulation and Anti Asthmatic action of the drugs.

#### SYRUP :

The drugs were administered in the form of Syrup, no medicine in other form than syrup is easily accepted by pediatric patients. In routine practice, children often reject even *Avaleha*, which is considered as the best in therapeutic forms for pediatric patients due to its palatability and acceptability. The decoction of the drugs was prepared, according to instructions given in *Sharangadhara Samhita*<sup>8</sup> and was converted into syrup form by adding 63% of *Khand Sharkara*

#### Probable mode of action of drug:

It is really very interesting for a scholar that the two combinations having almost opposite Ayurvedic pharmacological properties produce similar effect on a particular problem. The only probable explanation to this problem is that irrespective of *Rasa*, *Guna*, *Virya*, *Vipaka*; it is the active principle of a drug or a combination that work. In this regard the concept postulated by Acharya Charaka as

-----oh;± rq fØ;rs ;su lk fØ;k AA

Uk oh;± dq;rs fdfpar~ loZ% oh;Zd r% fØ;kAA

i.e., drug can't be do any action without potency or all action caused by potency.

Chakrapani the commentator of Charak Samhita states that, apart from *Rasa*, *Guna*, *Vipaka*; *Virya* is pre-eminently responsible for therapeutic action of a drug.

Acharya Vagbhata explains in this way the drug may act by virtue of its *Rasa*, any of its *Guna*, *Vipaka*, *Virya* or *Prabhava*. When this parameter also fails to explain the pharmacodynamics of a drug, then they tried to explain it in term of extra ordinary combination of five elements (Mahabhutas) in the drug i.e. "*Vichitrapratyayarabdha*".

Here Acharya Charaka introduce the concept of *Prabhava* i.e. when the two drugs differ with regard to their action, the distinctive feature responsible for distinctive effects not supported by their *Rasa*, *Vipaka* and potency is regarded as *Prabhava* or specific action.

Again Acharya Charaka introduces the concept of *Avayava Prabhava* and *Samudaya Prabhava* . i.e. because of the variation in the curative effect of drug, it affect action of one property of the drug by another and method of their preparation which leads to perversion or irregularity in combination, it is not possible to determine the attributes of a substance having many *Rasa*, simply by taking into account the attributes of individual *Rasa*.

From all these it could be concluded that the ancient Acharya`s realized a factor or group of factors in a drug or a combination which is solely responsible for the potency of the same.

#### Vasadi Syrup :

- It contains Vasa, Shunti, Kantkari, Guduchi and Sharkara. Majority of the ingredients having Tikta, Kashaya and Katu Rasa.
- Katu and Tikta Rasa drugs are known for its Deepana and Pachana properties. Due to Pachana properties drug makes Pachana of Ama along with its Deepana property. These both properties breaks the root cause of disease Tamaka swasa i.e. Mandagni.
- Katu and Kashaya Rasa due to its Shodhana property purifies the body
- In the other hand Tikta Rasa of the drug due to their Vishaghna and Krimighna property reduces the incidence and manifestation of allergy and infection of microorganism.
- Kapha Vata Shamaka property of the drug acts against the Tamaka Swasa by Hetupratyanika.
- They also have Rasayana property of drug also revitalizes and establishes good quality of *Sharira Dhatu*.
- According to modern pharmacology majority of drugs having an antimicrobial, antiviral and respiratory stimulant property which helps in the protection of individual against the pathogens.
- By these means the overall immunity is increased and in this way the capability of body to fight against pathogens gets naturally increased.

#### Satyadi syrup:

- In Satyadi syrup majority of drug having direct effect on *Pranavaha Srotas*. The impairment of *Pranavaha Srotas* i.e. produced by chronic and recurrent respiratory infection could effectively be ruled out by the drug which are expectorant, mucolytic and bronchodilator.
- The *Katu, Tikta Rasa Pradhana* drugs like *Maricha, Mishreya* etc. known for its *Deepana, Pachana Karma*. Due to *Pachana* properties drug makes *Pachana* of *Ama* along with its *Deepana* property. These both properties breaks the root cause of disease *Pratishyaya* i.e. Mandagni.
- *Katu* and *Kashaya Rasa* due to its *Shodhana* property purify the body .
- In the other hand *Tikta Rasa* of the drug due to their *Vishaghna* and *Krimighna* property reduces the incidence and manifestation of allergy and infection of microorganism.
- *Kapha Vata Shamaka* property of the drug acts against the *Pratishyaya* by *Hetupratyanika*.
- A good numbers of ingredients are having *Balya, Brimhana* and *Rasayana* properties. *Acharya Charaka* says that the drug having *Rasayana* property is able to cure the disease. Also revitalizes and establishes good quality of *Sharira Dhatu*.
- By these means the overall immunity is increased and in this way the capability of body to fight against pathogens gets naturally increased

#### Clinical study :

The research for finding a safe and cost effective *Ayurvedic drug*, to avoid side effects of long term treatment with corticosteroids which leads to osteoporosis, Growth suppression, obesity etc, for childhood asthma is the main theme for the present study entitled “**A Comparative Clinical Study to evaluate the effect of Vasadi Syrup and Satyadi Syrup in the management of Tamaka swasa w.s.r. to childhood asthma**”. Total 30 patients enrolled & completed the trial in the present study and the procured data was analysed.

#### Observations and Results:

##### 1. Age of the patient:

Age wise, the patients were classified into 3 groups. First group of age 3-6 year, 2nd group was 7-11 years and 3rd group ranging from 12-16 years. In the classical literature, ordinarily, we do not find a mention of the relation between *Tamaka Swasa* and age. Age wise distribution shows that the maximum numbers of patients were in age group 3-6 years (30.7%) and also in 7-11 (46%) years while in 12-16years have 23.3%. (Table no. 1) The data shows that the onset is common in childhood. Since, the *Tamaka Swasa* is a *Vata-Kapha* dominated disease, its incidence should be witnessed more either during the *Balyaavastha*, which is the normal time of *Kapha* dominance or the *Vridhdhavstha* which is the normal time of *Vata* dominance.

##### 2. Sex:

Sex wise distribution shows that maximum patients i.e. 90 % were males and 10% were females. **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<sup>4</sup>. It is broadly established that allergy in early life and in male infant and children is more prevalent<sup>5</sup>.

##### 3. Father's education:

Asthma management and control of Exacerbation depends largely on the care taken by the parents to provide 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. 60 % were graduated while 30% were HSC and 6.6% having education less than H.S.C and 3.3% were not educated.

#### 4. Socio-economic status:

Living conditions play a role in Asthma where environmental factors are aetiologically significant. Socio Economic status also has importance in providing hygienic living conditions to children. Majority of our patients in this study were from Middle Class Families (60%). 10% were from Upper Middle Class. 30% only were belonging to Lower class family and none of the patients were from the creamy layer of the society.

#### 5. Habitat:

Habitat profile of the registered patients reveals that maximum number i.e. 83% were from rural area while 17% patients were from urban area, as the study was conducted in rural area.

#### 6. Religion:

Religion wise distribution of patients shows maximum numbers of patients i.e. 96.6% were of Hindu religion while 3.33% were of Muslim religion. Higher frequency of Hindu children may be due to predominance of Hindu community in the study area. (Table no. 4)

#### 7. Hereditary influence:

Interestingly in the present study except for a minor percentage of 6.7% majority of the patients had a positive family history either from the maternal or paternal side

#### 8. Risk factors:

Table no.11 shows the risk factors in which major are genetic susceptibility (52%), use of antibiotic in early infancy<sup>7</sup>. (32.5%) followed by poor ventilation (27.5), passive smoking (25), pets (22.5), soft toys (12.5) & carpets (12.5) and early weaning (7.5). 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.

#### 9. Birth history:

The child born by caesarean section has more risk of asthma as compared to vaginal birth. It may be due to modified bacterial exposure during caesarian section<sup>8</sup> compared with vaginal birth that further modified the immune system.

In the study, 90% of children were delivered in Hospitals and 10% at home.

#### 10. Immunization status:

During the study, it was observed that 100 % of patients had received immunization at proper age because of social awareness and availability of facilities at govt. hospitals in the state.

#### 11. Diet:

Majority of the patients were consuming non-vegetarian food along with vegetarian food, figuring 93.4%. A small minority, 6.62% patients were vegetarians in the present study.

#### 12. Previous history of infectious diseases:

History of infectious diseases (Table no.17) revealed that the presence of Recurrent Upper Respiratory Tract Infections was found in 56.6% of patients in the present study. Constipation in 13.3%, Jaundice in 3.3% and Pneumonia in 10%, 16.6% were present Anaemia patients reported.

Which may be cause for the use of antibiotic in early life, a proven cause of respiratory allergic disorders<sup>9</sup>. The precipitating factor for an asthma attack 40% of the children is viral URTI<sup>10</sup>.

#### 13. 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 indicated classically as a Nidanarthakara roga in Tamaka Shvasa. In the present study 6.62% of patients reported. Krura Koshtha, 90% had Madhyama Koshtha and only 3.35% of patients were having Mridu Koshtha

**14. 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 Vata Pitta Prakrti scoring upto 23%. Pitta Kapha were comparatively less scoring up to 3%. KaphaVata Prakrti were 74 % .

As evident from the etiopathogenesis of *Tamaka swasa*, it is a *Kapha-vata pradhan* disease, therefore is more likely attack the individual with *Vata-kaphaprakriti*, also the severity will be more in these individual. This observation suggests that *Vata-kaphaprakriti* are more prone to bronchial asthma in children. (Table no. )

**15. Samhanan:**

*Dhatu asampoornata* makes the children poor in *Samhanana* also. Again relative assessment to age has been adopted here. More than half of the total patients showed *Avara Samhanan*, 3%, *Madhyama Samhanana* has been noted in 97% and not was found an *Uttama Samhanana*

**16. Satva:**

*Satwabala* is comparatively very low in kids. On the basis of *Klesha sahishnuta* and general nature of behavior, the patients in the study were classified into *Pravara, Madhya* and *Avara-Satwa*. 57.69% were of *Madhyama Satwa*, 15.38% were *Pravara-Satwa* and 26.93% were having *Avara Satwa*.

**17. Satmya:**

*Madhyamsatmya* was noted in maximum patient (52.5%) followed by (40%) *AvarSatmya* and *Pravar satmya* (7.5%) (Table No. ). This indicates *Asatmyata* to various substances like dust, environmental changes, food items drug etc. It leads to diminished tolerance capacity, resulting easily provoked/triggered by exposures.

**18. Vyayaam shakti:**

*Vyayaam shakti* wise distribution shows that 67.5% patients were having *Madhyam vyayaam shakti*, 20 % were having *Avara vyayaamshakti* and 12.5 % patients were having *Pravara vyayaamshakti*.

**Discussion regarding the effect of therapy:**

The study was conducted under two groups.

- ✓ Group I received *Vasadi syrup*.
- ✓ Group II received *Satyadi syrup*.

**Duration of trial** : 4 weeks.

**Dose:**3-6 year = 20 ml T.i.d.

7-11 year = 30 ml T.i.d.

12-16 year = 40 ml T.i.d.

A special Scoring system was adopted to assess improvement in various subjective/objective parameter and laboratory investigations before and after trial. Result obtained was statistically analyzed which is being discussed symptom wise here.

The effect of both the therapies in chief complain of the disease can be highlighted as follows –

**Table no - 10**

Symptoms	% relief with ‘P’ value			
	Group A		Group B	
<b>Kasa</b>	69.55%	<0.001	76%	<0.001
<b>Gurgaruktvamhm</b>	68%	<0.01	65.3%	<0.001
<b>Swasakrichrata</b>	78%	<0.001	56.4%	<0.01
<b>Use of accessory muscles</b>	83.3%	<0.01	60%	<0.01
<b>Anidra</b>	72.7%	<0.001	55.5%	<0.01
<b>Arati</b>	90.9%	<0.01	60.9%	<0.01
<b>Nasa srava</b>	78.9%	<0.001	68.4%	<0.001
<b>Vaktravairasya</b>	1%	<0.5	0.00	0.00

### 1. Effect on Coughing:

In group A the mean score of *Kasa* was 1.533 before treatment which was reduced to 0.467 after treatment with 69.55% relief. The mean score of *Kasa* in group B was 1.667 before treatment which was reduced to 0.400 after treatment with 76% relief. Both the result were statistically highly significant ( $P < 0.001$ ).

Statistically both the group showed highly significant relief and there was no statistically significant difference between BT and AT scoring of two groups ( $p > 0.05$ ). Though Group I showed 10.34% more relief than group II. Improvement in coughing can be attributed due to pacification of *Vata&Kapha dosha*, removal of the obstructing *Kapha* from the *pranavaha srotos* due to anti-tussive and mucolytic properties of trial drugs.

### 2. Effect on Gurgurtvham:

Before treatment the mean score of Gurgurktvham in group A was 1.667 which was reduced to 0.533 after treatment with 68% relief. The mean score of Gurgurktvham group B was 1.733 before treatment which was reduced to 0.600 after treatment with 65.3% relief. Both the results were statistically highly significant ( $P < 0.001$ ).

Statistically both the group showed highly significant relief and there was no statistically significant difference between BT and AT scoring of two groups ( $p > 0.05$ ). Though Group I showed 1.48% more relief than group II.

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

### 3. Effect on Swasakrichta :

In group A the mean score of swasakrichta was 1.400 before treatment which was reduced to 0.30 after treatment with 78% relief. The mean score of swasakrichta in group B was 1.400 before treatment which was reduced to 0.40 after treatment with 56.4% relief. The result was statistically highly significant in group 1 ( $P < 0.001$ ) but significant in group 2.

The Inter-group comparison over swasakrichta was statistically insignificant ( $p > 0.05$ ) although Group II showing 7.04% more relief than Group I.

### 4. Effect on Use of Accessory muscle:

Use of accessory muscles in group A the mean score was 1.200 before treatment which was reduced to 0.200 after treatment with 63.30% relief. The mean score of group B was 0.867 before treatment which was reduced to 0.133 after treatment with 60% relief. Both the result were statistically significant ( $P = 0.001$ ).

The Inter-group comparison over use of Accessory muscle was statistically insignificant. Though Group I showed 13.77% more relief than Group II.

### 5. Effect on Anidra

In group A the mean score of *Anidra* was 1.467 before treatment which was reduced to 0.40 after treatment with 72.00% relief. The mean score of *Anidra* in group B was 1.20 before treatment which was reduced to 0.53 after treatment with 55% relief. Both the result were statistically significant ( $P = 0.012$ ).

There was no statistically significant difference between BT and AT scoring of two groups ( $p > 0.05$ ). Though Group I showed 17.11% more relief than group II.

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

### 6. Effect on Arati :

In group A the mean score of Arati was 1.467 before treatment which was reduced to 0.40 after treatment with 90.9% relief. The mean score of Arati in group B was 1.40 before treatment which was reduced to 0.26 after treatment with 80.9% relief. Both the result were statistically highly significant ( $P < 0.001$ ).

There was no statistically significant difference between BT and AT scoring of two groups ( $p > 0.05$ ). Although Group I showed 9.85% more relief than Group II.

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

### 7. Effect on Vaktravairasya:

In group A the mean score of Vaktravairasya was 0.066 before treatment which was reduced to 0.00 after treatment with 1% relief. The mean score of Vaktravairasya in group B was 0.00 before treatment which was reduced to 0.00 after treatment with 0.00 relief. Both the result were statistically insignificant ( $P = 0.000$ ).

Statistically both the groups showed insignificant relief and in inter-group comparison, the result was statistically insignificant ( $p > 0.05$ ).

### 8. Effect on Nasasrava:

In group A the mean score of Nasasrava was 1.267 before treatment which was reduced to 0.267 after treatment with 78.9% relief. The mean score of Nasasrava in group B was 1.267 before treatment which was reduced to 0.400 after treatment with 68.4% relief. Both the result were statistically highly significant ( $P < 0.001$ ).



The intergroup difference was insignificant statistically ( $p>0.05$ ) Though Group I showed 13.77% more relief than group II.

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

#### 9. Effect of therapy on Respiration Rate

In group A the mean score was 0.867 before treatment which was reduced to 0.800 after treatment with 7.72% relief. The mean score of group B was 0.867 before treatment which was reduced to 0.800 after treatment with 7.72% relief. Both the result were statistically significant ( $P<0.01$ ).

But the intergroup difference was insignificant statistically ( $p>0.05$ ), Although Group II showed 2.74% more relief than Group I.

#### 10. Effect on PEFr:

In group A the mean score of PEFr was 1.692 before treatment which was reduced to 0.84 after treatment with 50.00% relief. The mean score of PEFr in group B was 1.84 before treatment which was reduced to 1.1 after treatment with 37.48% relief. Both the result were statistically highly significant ( $P<0.001$ ).

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

#### 11. Effect on Oxygen saturation:

In group A the mean score was 0.800 before treatment which was reduced to 0.667 after treatment with 25.00% relief. The mean score of group B was 0.86 before treatment which was reduced to 0.33 after treatment with 62.4% relief. Both the result were statistically significant ( $P<0.01$ ).

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

#### 12. Effect of therapy on Laboratory parameters -

Except for AEC count the hematological parameters in group A and group B were within normal limits both before and after the therapy and statistically insignificant changes ( $p>0.05$ ) were observed in these values after the completion of therapy.

The mean scores obtained before trial in case of Eosinophil count were 7.23 both in group A and in group B which after trial were reduced to 5.30 and 5.15 respectively. The percentage improvement in group I was 26.55 % and 28.63 % in group II which was statistically significant in both groups ( $p<0.01$ ).

In group A the mean score of AEC was 0.046 before treatment which was reduced to 0.022 after treatment with 52.00% relief. The mean score of AEC in group B was 34.7% before treatment which was reduced to 0.030 after treatment with 74.19% relief. Both the result were statistically highly significant ( $P<0.001$ ).

Eosinophil's 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 the inflammation and relieving bronchoconstriction after the therapy.

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