A Comparative Clinical Study to evaluate the effect of Drakshadi avleha and Vasadi Syrup in the management of Tamaka swasa w.s.r. to childhood asthma

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Abstract- **The most prevalent chronic lung condition is Asthma, which has been acknowledged as one of the worst health issues in the world. Mortality has increased as well, especially in the young age group. The prevalence of the condition declines with increasing age. The most obvious aspect of life that *Prana Vayu* performs is breathing. It gives people energy and is a sign of mindfulness. This condition, *Tamaka Shwasa*, impairs the respiratory function by affecting this one and only indication of life. *Asthma* has received a lot of attention recently due to its fast rising prevalence. 100 to 150 million children worldwide suffer from this non-communicable respiratory condition, despite the use of both cutting-edge modern medication and centuries-old traditional medicine. According to the International Study of Asthma and Allergy in Childhood (ISAAC), asthma prevalence in India is expected to be 6.2%–6.8% in children aged 6-7 and 6.4%–6.7% in children aged 12–16, with more males than females afflicted. It is a chronic condition of the *paranvaha srotas*, with *pitta sthan*a as the primary genesis and vitiation of the *kapha* and *vata doshas*.Dyspnea *(swasakrichrata)*, chest tightness *(urashula)*, wheezing *(Gurgaruktvamhm)*, and coughing *(kasa)* are the symptoms of *tamaka shwasa*.The paroxysm episode impairs the child's daytime functioning and disrupts their usual sleep patterns at night. School absences, as well as social, economic, and psychological effects on the family, are all caused by childhood asthma. Even though *Tamaka Shwasa* is regarded as *Yapya Vyadhi*, its early stages can be treated. There are several anti-asthmatic medications available today that can successfully treat asthma paroxysms, but they are unable to manage many side effects. The development of low-cost asthma management programmes is also necessary to guarantee that asthma care is accessible and inexpensive for people from all socioeconomic backgrounds. The purpose of the current study is to assess the efficacy of two *Ayurvedic* formulations taking into account all of these factors.Due to its *Vata-Kaphahara, Swasahara,* and *Rasayana* qualities, the *Drakshadi Avleha* and *Vasadi Syrup* formulation was chosen.**

AIM: The study to evaluate the effect of *Drakshadi Avleha* and *Vasadi Syrup* in the management of *Tamaka Shwasa* w.s.r. to Childhood Asthma.

METHOD: The diagnosis procedures, inclusion and exclusion criteria for the patients, and symptoms associated with *Bala Tamaka shwasa* were used. To confirm the diagnosis, essential examinations were done.A minimum sample of 40 patients in both groups were assessed during the trial for 30 days with follow-up of 15 days. Selected patients were divided into two groups. Group I- 20 patients and Group II- 20 patients. The patients were selected from the OPD of Major S.D. Singh Ayu. Medical College Bewar Road, Farrukabad (U.P.).

RESULT: Both medications have a noticeable impact on the treatment of *Bala Tamaka shwasa* symptoms and major adjustments to research & significant changes in investigations.

CONCLUSION: *Drakshadi Avleha* and *Vasadi syrup* can be used to successfully treat *Tamaka Shwasa* and avoid complications.

Keywords: **Bronchial Asthma, Tamaka shwasa, Drakshadi Avleha, Vasadi Syrup.**

INTRODUCTION

Ayurveda has been a holistic alternative science for ages and is known as the "science of life" or longevity. *Ayurveda's* whole concept is built on obtaining, maintaining, and promoting good health. Health is the outcome of the balance of the body's numerous structural and functional units, including *Dosha, Dhatu, Mala, Agni, and Mana*. Humans' shifting dietary and behavioural habits cause an imbalance in their bodies, which then manifests as illness.One of them, *shwasa roga*, is becoming more common nowadays owing to a number of circumstances, including modified eating habits, environmental pollution, stress and strain, and altered lifestyles. The most obvious aspect of life, which is carried out by *Prana Vayu*, is respiration[1]. It gives people energy and is a sign of mindfulness.This condition, *Tamaka Shwasa*, which is similar to bronchial asthma, affects this one and only sign of life, impairing respiratory function. With rising urbanisation, the number of children with asthma may increase by 100 million by 2025. There is an estimated 1–18% prevalence of asthma in children. According to the International Study of Asthma and Allergy in Childhood (ISAAC), asthma prevalence in India is expected to be 6.2%–6.8% in children aged 6-7 and 6.4%–6.7% in children aged 12–16, with more males than females afflicted. It ranks as the third most common reason for hospitalisation for patients under the age of 15[2]. *Ayurveda* and modern medicine both believe that the host factors (*Nija Hetu's-Doshadushti* and *Ama*) and environmental variables (*Agantuja Hetu's-Raja, Dhuma, Pragvata*, etc.) are the causes of the disease[3].

Kaumarbhritya, one of *Ayurveda's Astangas*, focuses particularly on issues relating to newborns and young children. The fact that *Ayurvedic* paediatric care begins at conception is a special characteristic of this healing system. It covers prenatal, perinatal, and postpartum care in addition to the various facets of child health and illness. *Kashyap samhita* is the main literary text available that deals with *garbha, bala* and *kumara*. The word *Tamaka Shwasa* is found in *Khilsthana* chapter 10.
Tamaka shwasa is one of the five varieties of *shwasa* listed in the *Charaka Samhita*. It is a chronic condition of the *paranvaha srotas*, with origins in the *pitta sthana* and a vitiation of the *kapha and vata doshas* in particular[4]. Dyspnea (*swasakrichrata*), chest tightness *(urashula*), wheezing (*Gurgaruktvamhm*), and coughing (*kasa*) are the symptoms of *tamaka shwasa*[5]. 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*[6] but it is curable in its initial phase. The paroxysm episode impairs the child's daytime functioning and disrupts their usual sleep patterns at night. School absences, activity restrictions, social, economic, and psychological effects on the family are all caused by childhood asthma. The purpose of the current study is to assess the efficacy of two *Ayurvedic* formulations taking into account all of these factors. Due to its *Vata-Kaphahara, Swasahara, Rasayana* and immune-modulator characteristics, the formulations *Drakshadi avleha*[7] (containing *Draksha, Krikatshringi, Haritaki, Pippali, and Duralaba)* and *Vasadi Syrup*[8] *(containing Vasa, Shunti, Kantakari*, and *Guduchi*) have been chosen. The formulation is simple to use, readily available, affordable, and has a small number of components.

AIMS AND OBJECTIVES

- To review the *Ayurvedic* and Modern literature related to *Tamaka shwasa.*
- To compare the effect of *Drakshadi avleha* and *Vasadi Syrup* in the management of *Tamaka shwasa* in children.
- To establish a safe and cost effective medicine for the treatment of *Tamaka shwasa*.
- To find out the merit & demerits of the trial drugs.

PLAN OF STUDY

Research work will be planned in the following way:

➢ Conceptual study
➢ Clinical study

Conceptual study: We critically analyse the literature on experimental medications as well as the material on *Bala Tamaka shwasa* in relation to paediatric asthma.

Clinical study: The focus of the suggested research effort was on this. The diagnosis procedures, inclusion and exclusion criteria for the patients, and symptoms associated with *Bala Tamaka shwasa* were used. To confirm the diagnosis, essential examinations were done.A minimum sample of 40 patients in both groups were assessed during the trial for 30 days with follow-up of 15 days. Selected patients were divided into two groups. Group I- 20 patients and Group II- 20 patients. The patients were selected from the OPD of Major S.D. Singh Ayu. Medical College Bewar Road, Farrukabad (U.P.).

RESEARCH PROTOCOL

Consent of the parents/guardians of the patient

Before the experiment, the patient's parents or guardians will be asked for their written, informed permission. Grouping of patients: Selected patients will be divided into two groups. Group I- 20 patients Group II- 20 patients.

Group I	*Drakshadi avleha*
Group II	*Vasadi syrup*

The Drugs were prepared in the Major S.D. Singh Ayu. Medical College Bewar Road, Farrukabad (U.P.) under the supervision of dept. Of *Rasa-shastra and Bhaishajyakalpana.*

Trial Drug

The present clinical study is planned to evaluate and compare the effect of *Drakshadi Avleha and Vasadi syrup*.

➢ *Drakshadi Avleha*

Sr. No	Name	Botanical name	Family	Part used
1	*Draksha*	Vitis vinifera Linn.	Vitaceae	Fruit
2	*Haritaki*	Terminalia chebula Retz.	Combretaceae	F.pericarp
3	*Pippali*	*Piper longum Linn.*	Piperaceae	Fruit

4.	*Krikatshringi*	*Pistacia integerrima*	Anacardiaceae	Gall
5	*Duralabha*	*Fagonia cretica Linn.*	Zygophyllaceae	Whole Plant
6	*Madhu*			
7.	*Ghrita*			

➢ *Vasadi syrup*

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

DOSES AND DURATION

➢ Patients in Group- I were managed with *Drakshadi Avleha* for a duration of 4 Weeks.

➢ Patients in Group- II were managed with *Vasadi Syrup* for a duration of 4 weeks.

Doses

Age	**Group I**	**Group II**
3-6 years	1-1.5gm T.i.d	20ml/day in three divided doses
7-11 years	3gm T.i.d	30ml/day in three divided doses
12-16 years	4gm T.i.d	40ml/day in three divided doses

Duration of trial: 4 weeks with follow up of 7^{th},15^{th},30^{th} day of management. A special Scoring system was adopted to assess improvement in various subjective/objective parameters and laboratory investigations before and after trial.

STUDY SCHEDULES

➢ **Screening**

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

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

➢ **Enrollment**

Selection of patients: Patients were selected from the OPD/IPD of Major S.D. Singh Ayu. Medical College Bewar Road, Farrukabad (U.P.) 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 16 years.

- Only mild to moderate stable patients of childhood asthma were included.
- Positive test of reversibility in Oxygen saturation, PEFR in children.

Exclusion criteria:

- Parents of the patients not willing to participate in the trial.
- Patient having severe childhood asthma/ Status asthmaticus condition.
- Patients presenting systemic illness like pneumonitis, pleural effusion, pulmonary T.B. etc.
- Children with congenital anomalies.
- Patients with PEFR < 50% and FEV1 <50%.
- Patient on prolonged medication with corticosteroids, bronchodilators, mast cell stabilisers, anticholinergics etc.

Assessment criteria:

- Patient were thoroughly assessed on the basis of detailed medical history, family history, H/o eczema/atopic 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 broncho-dialators.
- Clinical assessment by objective parameters like:
- Oxygen saturation- in younger children less than 6 years
- Peak expiratory flow rate

➢ **Follow up**

Follow up of 7^{th},15^{th},30^{th} day of management and after completion of trial.

LABORATORY INVESTIGATION

The laboratory Investigations were done before and after the trial.

Blood test	Hb gm%, TLC, DLC, ESR, AEC
PEFR	Above the age of 6 years.
Oxygen saturation	Below and above the age of 6 years

CRITERIA OF ASSESSMENT

Assessment of subjective parameters (clinical features) and objective parameters depending on severity was done as four point scale : Nil 0 : Mild 1: Moderate 2 : Severe 3

Symptom	**Scoring**
Subjective parameters	
Cough *(Kasa)*	0: No cough, 1:Intermittent cough, 2: Persistent coughing provoked with exercise, 3: Continuous coughing with chest pain
Wheezing *(Ghurguratvam)*	0: None, 1:Mild wheezing, 2: Moderate wheezing, 3: Severe wheezing
Dyspnoea *(Swasakrichrata)*	0: No breathlessness with coughing, 1:Breathlessness on mild exercise, 2: Breathlessness provoked with moderate exercise, 3: Continuous breathlessness
Use of accessory muscles (Sternomastoid activity)	0: No apparent activity, 1: Mild retraction, 2: Moderate retraction, 3: Severe retraction
Sleep disturbance *(Anidra)*	0: No sleep disturbance, 1: Little interruption with coughing, 2: Moderate interruption with exacerbation, 3: Frequent sleep disturbance
Restlessness *(Arati)*	0: No difficulty in speaking, 1:Mild difficulty in speaking, 2: Moderate difficulty in speaking, 3: Severe difficulty in speaking
Nasal discharge *(Nasasrava)*	0: No discharge, 1: Running nose without visible fluid, 2: Running nose with visible fluid, 3: Continuous discharge with copious fluid
Colour of face *(Vakravairasya)*	0: Pink, 1: Pale, 2: Ashen grey, 3: Cyanotic (bluish)

Objective parameters	
Respiration rate	i) Children below 6yr - 0: Less than 30/min, 1: 31-45/min, 2: 46-60/min, 3: >60/min ii) Children >6yr - 0: <20/min, 1: 21-35/min, 2: 36-50/min, 3: >50/min
PEFR	0: More than 90%, 1: 70- 90%, 2: 50-70%, 3: Less than 50%
SpO2	0: >95%, 1: 76-95%, 2: 51-75%, 3: <50%

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.

OBSERVATIONS & RESULTS

In the present study, 40 patients were registered and 36 of them completed the trial, 4 patients dropped out.

The observations are on demographic data of 40 patients are as under

S. No.	**Criteria**	**Observations**
1	Age profile	Age wise distribution shows that the maximum numbers of patients were in the age group 3-6 years (35%) and also in 7-11 (35%) years while in 30% 12-16 years.
2	Sex profile	Sex wise distribution shows that maximum patients i.e. 70 % males and 30% females.
3	Education profile	Maximum numbers of patients i.e. 65% were School going students while 35 % were preschool children.
4	Father's Education Profile	Father‟s of maximum no. of patients i.e. 37.5% were graduated while 32.5% were HSC and 22.5% had education less than H.S.C and 7.5% were not educated.
5	Father'sOccupation wise	Fathers of maximum patients i.e. 44 % were businessmen and private jobs, followed by 40 % in the government. service and 16 % were labourers.
6	Socio-economic profile	Maximum no of patients i.e. 65% belonged to middle class family. While 25% belong to the lower class followed by 10% belonging to the upper class.
7	Habitat profile	Habitat profile of the registered patients reveals that the maximum number i.e.84% were from rural areas while 16% patients were from urban areas.
8	Religion profile	Maximum numbers of patients i.e. 96% were of Hindu religion while 4% were of Muslim religion.
9	Source of Water Profile	Maximum numbers of patients i.e. 82.5% were using municipal water while 17.5% were using others.
10	Hereditary influence profile	Hereditary influence was present in 57.5% patients.
11	Risk factors profile	The present study reveals that genetic susceptibility (52%) and (32.5%) were of use of antibiotic in early life major risk factors in patients of bronchial asthma followed by poor ventilation, passive smoking, pets, soft toys & carpets and early weaning.
12	Birth History profile	Maximum i.e. 67.5% patients were having history of normal delivery, while 27.5% patients had a history of caesarean section and 5% were having forceps one.
13	Birth Weight profile	72.5% patients were having a history of normal birth weight while 27.5% were having a history of low birth weight.

14	Immunization status profile	Immunization profile of registered patients reveals that all the patients were properly immunized.
15	Type of Diet Profile	Maximum no. of patients i.e. 52.5 % of patients were taking both vegetarian and non-vegetarian while 47.5 % were vegetarians.
16	Aggravating Cause's Profile	In the present study aggravating factors for most of the patients were Cold air or cold season, smoke, seasonal changes, dust and pollen followed by cold drinks, cloudy weather, and mental stress respectively.
17	Previous H/O infectious illness profile	History of infectious diseases in registered patients reveals that H/o RURTI was present in all the patients whereas h/o pneumonia present in 45% patients followed by gastroenteritis, typhoid and jaundice respectively.
18	Koshtha Profile	65% patients had Madhyama koshtha followed by 20% patients having Krura koshtha and 15% patients had Mridu koshtha.
19	Prakriti Profile	80 % patients were of Vata kaphaj prakriti while 12.5 % were of Vata pittaja and 7.52% patients were of Pittaja kaphaja prakriti.
20	Mansik Prakriti Profile	70% patients were of Satvika prakriti while 15 % were of Rajasa prakriti and Tamsika Prakriti.
21	Samhanana profile	62.5 %patients were of Madhyama samhanan, 22.5% were of Avara samhanana and 15 % patients were of Pravara samhanana.
22	Satva profile	60 % were of Madhyama satva, 30 % patients were of Avara satva and 10% patients were of Pravara satva.
23	Satmya profile	52.5% patients were of Madhyama satmya, 40% were of Avara satmya and 7.5% patients were of Pravara satmya.
24	Vyayaam profile	67.5% patients were having Madhyama vyayaam shakti, 20 % were having Avara vyayaam shakti and 12.5 % patients were having Pravara vyayaam shakti.

EFFECT OF THERAPY

Clinical observations are related to 18 patients in each group 1 and Group II who completed the treatment for the entire duration.

Effect of therapy on the basis of subjective criteria

S.No	Clinical features	Group	N	Mean		% Change	± SD	± SE	't'	P
				BT	AT					
1	*Kasa*	I	18	2.389	1.333	44.20	0.639	0.151	7.007	<0.001
		II	18	2.444	1.111	54.54	0.485	0.114	11.662	<0.001
2	*Gurguratvam*	I	18	2.000	1.000	50.00	0.343	0.080	12.369	<0.001
		II	18	1.944	1.000	48.55	0.416	0.089	9.628	<0.001

3	*Swasakrichata*	I	18	1.889	1.278	32.34	0.502	0.118	5.169	<0.001
		II	18	1.833	1.111	39.38	0.461	0.109	6.648	<0.001
4	Use of accesory muscles	I	11	1.182	1.545	53.80	0.505	0.152	4.183	<0.01
		II	13	1.154	0.692	40.03	0.513	0.144	3.207	<0.01
5	*Anidra*	I	15	1.533	0.667	56.55	0.640	0.165	5.245	<0.001
		II	13	1.462	0.385	73.66	0.494	0.137	7.867	<0.001
6	*Arati*	I	15	1.067	0.200	81.25	0.352	0.090	9.539	<0.001
		II	13	1.077	0.308	71.40	0.439	0.122	6.325	<0.001
7	*Nasasrava*	I	11	1.545	0.727	52.94	0.405	0.122	6.708	<0.001
		II	14	1.786	0.714	59.96	0.267	0.071	15.00	<0.001
8	*Vakravairasaya*	I	11	1.182	1.545	53.80	0.505	0.152	4.183	<0.01
		II	13	1.154	0.692	40.03	0.513	0.144	3.207	<0.01

Intergroup comparison over symptoms

S.No	**Parameter**	**Gr. I**	**Gr. II**	**%relief difference**	**S.D.±**	**S.E. ±**	**'t'**	**P**	**Result**
1	*Coughing*	18	18	10.34	2.733	0.86	0.32	>0.05	N.S.
2	*Wheezing*	18	18	1.45	1.48	0.492	0.11	>0.05	N.S.
3	*Swasakrichata*	18	18	7.04	0.494	0.164	0.676	>0.05	N.S.

4	Use of accessory muscles	11	13	13.77	0.432	0.177	0.9830	>0.05	N.S.
5	*Anidra*	15	13	17.11	0.523	0.197	1.062	>0.05	N.S.
6	*Arati*	15	13	9.85	0.359	0.135	0.722	>0.05	N.S.
7	*Nasasrava*	11	14	7.02	0.286	0.115	2.2	<0.05	S.
8	*Vakravairasaya*	11	13	13.77	0.432	0.177	0.9830	>0.05	N.S.

Effect of therapy on the basis of objective criteria

S. No.	Clinical features	Group	N	Mean		% change	± SD	± SE	T	P
				BT	AT					
1	Respiration rate	I	18	1.833	1.056	42.44	0.428	0.101	7.714	<0.001
		II	18	1.722	0.944	45.18	0.458	0.129	6.018	<0.001
2	PEFR	I	13	1.692	0.846	50.00	0.376	0.104	8.124	<0.001
		II	13	1.846	1.154	37.48	0.480	0.133	5.196	<0.001
3	Oxygen Saturation	I	18	1.000	0.444	44.40	0.515	0.121	3.688	<0.01
		II	18	1.000	0.667	33.30	0.485	0.114	2.915	<0.05

Intergroup comparision over parameters

S.No.	**Parameter**	**Gr. I**	**Gr. II**	**%relief difference**	**S.D.±**	**S.E. ±**	**'t'**	**P**	**Result**
1	Respiration rate	18	18	2.74	0.504	0.168	0	>0.05	N.S.

2	PEFR	13	13	2.16	0.376	0.146	1.05	>0.05	N.S.
3	Oxygen Saturation	18	18	11.1	0.511	0.170	0.652	>0.05	N.S.

Effect on Laboratory investigations in Group-I

Clinical Feature	**N**	**Mean Score**		**% Diff.**	**SD ±**	**SE ±**	**'t'**	**P**
		BT	**AT**					
Hbgm%	18	11.57	12.30	6.23	1.543	0.364	1.986	>0.05
TLC	18	8661.11	8722.2	0.7	3316.2	781.658	0.078	>0.05
Neutrophil	18	41.58	49.08	18.03	19.38	5.59	1.34	>0.05
Lymphocyte	18	47.50	40.75	14.21	17.75	5.12	1.31	>0.05
Monocyte	18	3.25	4.58	40.92	4.53	1.30	0.76	>0.05
Eosinophil	18	7.23	5.30	26.55	2.17	0.60	3.18	<0.05
ESR	18	10.91	10.66	2.29	4.41	1.27	0.19	>0.05
AEC	18	440.889	315.444	28.45	45.077	10.625		11.80 <0.001

Effect on Laboratory investigations in Group-II

Clinical Feature	**N**	**Mean Score**		**% diff.**	**SD ±**	**SE ±**	**'t'**	**p**
		BT	**AT**					
Hbgm%	18	11.81	12.72	7.66	1.336	0.315	2.87	<0.05
TLC	18	8083.33	7416.67	8.2	1412.54	332.94	2.002	>0.05
Neutrophil	18	58.53	57.53	1.70	10.05	2.79	0.35	>0.05
Lymphocyte	18	30.53	31.92	4.52	9.60	2.66	0.52	>0.05
Monocyte	18	3.53	4.76	34.84	4.51	1.25	0.98	>0.05
Eosinophil	18	7.23	5.15	28.63	2.29	0.63	3.27	<0.05

ESR	18	11.25	7.7	31.11	5.89	2.16	1.61	>0.05
AEC	18	384.556	340.00	11.58	20.566	4.847	9.191	<0.001

Overall Effect of Therapy

The results of two drugs were evaluated on the basis of criteria established for assessment of the results. Overall percentage improvment of each patient was calculated by the following Formula: BT − AT/BT *100

The patients were categorized into markedly improved, moderately improved, mildly improved and unchanged according to assessment criteria.

Result	**Group-I**		**Group-II**	
	No. of Patients	**%age**	**No. of Patients**	**%age**
Complete Remission	0	0	0	0
Markedly Improved	1	5.5	2	11.11
Moderately improved	11	61.11	10	55.55
Mildly Improved	6	33.33	6	33.33
No improvement	0	0	0	0

In the ***Drakshadi Avleha*** group (18 patients)marked improvement in 5.5%, moderate improvement in 61.11%, mild improvement in 33.33% of patients. While in ***Vasadi Syrup*** group (18 patients), marked improvement was seen in 11.11% of patients, moderate improvement in 55.55%, mild improvement in 33.33% of patients.

DISCUSSION

➢ **Discussion on Conceptual Study**

Shwasa 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* is the main among these five types for management point of view. *Tamaka Shwasa* is a disease in which the *vayu*, which is vitiated and blocked by *kapha*, moves upward instead of its normal flow to the *uras*[9]. In the *samprapti* of *Tamaka shwasa*, Acharyas have explained the *dushti* of *prana*, *udaka* and *anna vahini srotamsi*[10]

➢ **Discussion on Clinical Study**

Total 40 patients enrolled & completed the trial in the present study and the procured data was analyzed.

Discussion on Observations and Results:

- **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 (35%) and also in 7-11 (35.1%) years while in 12-16years have 30%. (Table no. 1) The data shows that the onset is common in childhood. The WAC and GINA also classified children under the age of 5yr are the most vulnerable age group in childhood asthma requiring very special and gentle care.

- **Sex**

Sex wise distribution shows that maximum patients i.e. 70 % were males and 30 % 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.

- **Father's education**

Asthma management and control of Exacerbation depends 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. Majority were literate except 3 who were illiterate. An educated parent can be easily educated about the need of, monitoring of symptoms, proper administration of medication and regular follow up with *Nidana parivarjanam* and *pathyapathya*. Thus, a parental education status survey was done among the registered patients. Father"s of maximum no. of patients i.e. 37.5% were graduated while 32.5% were

HSC and 22.5% having education less than H.S.C and 7.5% were not educated.

- **Socio-economic status**

Maximum no of patients i.e. 65% belonged to middle class family,25% belonged to the lower class followed by 10% belonging to the upper class. Socioeconomic status has an effect on a child‟s response to illness. If they are poor and the diet is inadequate, the child's resistance will be lower.

- **Habitat**

Habitat profile of the registered patients reveals that the maximum number i.e. 95% were from rural areas while 5% patients were from urban areas, as the study was conducted in rural areas.

- **Religion**

Religion wise distribution of patients shows maximum numbers of patients i.e. 96% were of Hindu religion while 4 % were of Muslim religion. Higher frequency of Hindu children may be due to the predominance of Hindu community in the study area.

- **Source of water**

Source of water wise distribution (Table No.9) showed that maximum numbers of patients i.e. 82.5% were using municipal water while 17.5% were using others.

- **Hereditary influence**

Hereditary influence was present in 57.5% patients. It supports the genetic contribution in the development of bronchial asthma. A critical review of the literature on *Tamaka Swasa* reveals that the disease travels from one generation to the other generation. Role of hereditary factors in Asthma has been elicited by various studies recently. Absence of NRF2 gene has been found to increase the number of inflammatory cells within the airways, causing the airway lining to swell which induces asthma in mice.

- **Risk factors**

The risk factors in which major are genetic susceptibility (57.5%), use of antibiotics in early infancy. (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). Parental cigarette smoking has been shown to increase the likelihood of asthma.

- **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 caesarean section

- **Birth weight**

Low birth weight babies are prone to develop malnutrition and recurrent infections in later life. But present study shows 72.5% patients were having a history of normal birth weight while only 27.5% were having a history of low birth weight.

- **Immunization status**

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

- **Diet**

Maximum no. of patients i.e. 52.5 % of patients were taking both vegetarian and non vegetarian while 47.5 % were vegetarians.

- **Aggravating factors**

In the present study aggravating factors for most of the patients were Cold air or cold season, smoke, seasonal changes, dust and pollen followed by cold drinks, cloudy weather, and mental stress respectively.

- **Previous history of infectious diseases**

History of infectious diseases revealed that the maximum patient were having history of RURTI(100%), Gastroenteritis (40%), pneumonia (45%), followed by typhoid(35%) and jaundice(15%) which may be cause for the use of antibiotic in early life, a proven cause of respiratory allergic disorders.

- ***Koshtha***

65% patients had *Madhyama koshtha* followed by 20% patients having *Krura koshtha* and 15% patients had *Mridu koshtha*.

- ***Prakriti***

Proper *Prakrti* analysis is difficult in children because of '*Sarva dhatu asampoornata'.* Still an attempt has been made to analyse the *Prakrti* on the basis of current behaviour, physical features and other physical characters. In this study *Prakriti* wise distribution of patient shows that there was predominance of *Vata-kapha prakriti* (80%).

- ***Mansik prakriti***

Mansik prakriti wise distribution shows that 70% patients were of *Satvika prakriti* while 15% were of *Rajas prakriti.*

- ***Samhanan***

62.5% patients were of *Madhyama samhanan,* 22.5% were of *Avara samhanana* and 15 % patients were of *Pravara samhanana.*

- ***Satva***

Madhyama satva was noted in the maximum, however, accounting to 60 % followed by *Avar satva* (30%) and *Pravara satva* (10 %).

- ***Satmya***

Madhyam satmya was noted in maximum patients (52.5%) followed by (40%) *Avar Satmya* and *Pravar satmaya* (7.5%)

- ***Vyayaam shakti***

67.5% patients were having *Madhyam vyayaam shakti,* 20 % were having *Avara vyayaam shakti and* 12.5 % patients were having *Pravara vyayaam shakti.*

➢ **Discussion regarding the effect of therapy**

The study was conducted under two groups.

- Group I received Drakshadi Avleha,
- Group II received Vasadi Syrup

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

Symptoms	**% relief with 'P' value**			
	Group I		**Group II**	
Kasa	44.20%	<0.001	54.54%	<0.001
Gurgaruktvamhm	50%	<0.001	48.55%	<0.001
Swasakrichrata	32.34%	<0.001	39.38%	<0.001
Use of accessory muscles	53.88%	<0.01	40.03%	<0.01
Anidra	56.55%	<0.001	73.66%	<0.001
Arati	81.25%	<0.001	71.40%	<0.001
Nasa srava	52.94%	<0.001	59.96%	<0.001
Vaktravairasya	53.80%	<0.01	40.03%	<0.01

1. Effect on Coughing(Kasa):
The mean scores obtained before the trials in group I and II were 2.389 and 2.444 and after trial the mean scores were reduced to 1.333 and 1.111 respectively. The percentage relief was 44.20% in group-I which was statistically highly significant ($p<0.001$).The percentage relief in group-II was 54.54% which was also 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-II showed 10.34% more relief than group-I. Improvement in coughing can be attributed due to pacification of *Vata* & *Kapha dosha*, removal of the obstructing *Kapha* from the *pranavaha srotos* due to antitussive and mucolytic properties of trial drugs.

2. **Effect on Wheeze (Gurgaruktvamhm):**
The mean scores obtained before the trials were 2.000 and 1.944 and after trial were reduced to 1.000 and 1.000 in group I and II respectively. The percentage relief was 50.00 % in group-I which was statistically highly significant ($p<0.001$).The percentage relief in group-II was 48.55% which was also 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 Dyspnoea (Swasakrichrata):
The mean scores obtained before the trial in group I and II were 1.889 and 1.833 and after trial 1were reduced to 1.278 and 1.111 respectively. The percentage relief was 32.34% in group-I which was statistically highly significant ($p<0.001$).The percentage relief in group-II was 39.38 % which was also statistically highly significant ($p < 0.001$). The Inter-group comparison over dyspnoea was statistically insignificant ($p>0.05$) although Group-II showed 7.04% more relief than Group-I.

4. Effect on Use of Accessory muscle:
The mean scores obtained before the trial in group-I and II were 1.182 and 1.154 and after trial were reduced to 1.545 and 0.692 respectively. The percentage relief was 53.80 % in group-I which was statistically highly significant ($p<0.01$).The percentage relief in group-II was 40.03% which was also statistically highly significant ($p < 0.01$). 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 sleep disturbance(Anidra):
The mean scores obtained before the trial in group-I and II were 1.533and 1.462 and after trial were reduced to 0.667and 0.385 respectively. The percentage relief was 56.55% in group-I which was statistically highly significant ($p<0.001$).The percentage relief in group-II was 73.66% which was also statistically highly significant ($p < 0.001$). There was no statistically significant difference between BT and AT scoring of two groups ($p>0.05$).Though Group-II showed 17.11% more relief than Group-I.
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 Restlessness (Arati):
The mean scores obtained before the trial in group-I and II were 1.067and 1.077 and after trial were reduced to 0.200 and 0.308 respectively. The percentage relief was 81.25% in group-I which was statistically highly significant ($p<0.001$).The percentage relief in group-II was 71.40% which was also highly statistically 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 Rhinorrhoea(Nasa srava):
The mean scores obtained before the trial in group A and B were 1.545and 1.786 and after trial were reduced to 0.727 and 0.714 respectively. The percentage relief was 52.94% in group A which was statistically highly significant ($p<0.001$).The percentage relief in group B was 59.96% which was also statistically highly significant ($p < 0.001$) Statistically both the groups showed highly significant relief and in inter-group comparison, the result was statistically insignificant ($p>0.05$)

8. **Effect on Face colour(Vaktravairasya):**
The mean scores obtained before the trial in group I and II were 1.182 and 1.154 and after trial were reduced to 1.545 and 0.692 respectively. The percentage relief was 53.80 % in group I which was statistically highly significant ($p<0.01$).The percentage relief in group II was 40.03% which was also statistically highly significant ($p < 0.01$). 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 haemoglobin.

9. Effect of therapy on Respiration Rate:
The mean scores obtained before the trials were 1.833 and 1.722 and after trial were reduced to 1.056 and 0.944 in group I and II respectively. The percentage relief was 42.44 % in group I which was statistically highly significant ($p<0.001$).The percentage relief in group II was 45.18% which was also statistically highly significant ($p < 0.001$). 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:
The mean scores obtained before the trials were 1.692 and 1.846 and after trial were reduced to 0.846 and 1.154 in group I and II respectively. The percentage relief was 50 % in group I which was statistically highly significant ($p<0.001$).The percentage relief in group II was 37.48% which was also statistically highly significant ($p < 0.001$). The intergroup difference was insignificant statistically ($p>0.05$). But Group I showed 2.16% more relief than Group II. The improvement PEFR indicates that the trial therapy is capable of modifying the existing airflow limitations caused by obstruction due to *Samakapha* in these patients.

11. Effect on Oxygen saturation:
The mean scores obtained before the trials were 1.000 and 1.000 and after trial were reduced to 0.444 and 0.667 in group I and II respectively. The percentage relief was 44.40 % in group I which was statistically significant ($p<0.01$).The percentage relief in group II was 33.30% which was also statistically significant ($p < 0.05$). The intergroup difference was insignificant statistically ($p>0.05$). Although Group I showed 11.1% more relief than in Group II. 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 Eosinophil count and AEC count the haematological parameters in group I and group II 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 I and in group II 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 ($p<0.01$).

The mean scores obtained before trial in case of AEC count were 440.889 in group I and 384.556 in group II which after trial were reduced to 315.444 and 340.00 respectively. The percentage improvement in group I was 28.45 % and 11.58 % in group II which was highly significant in both groups ($p<0.001$). 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 the inflammation and relieving bronchoconstriction after the therapy.

➢ **Discussion on mode of action of trial drug:**

Drakshadi Avleha*:Drakshadi Avleha* has *Madhura Rasa* dominance along with *Kashaya Tikta, Katu*, and *Kashaya Rasa*. *Tikta, Katu* & *Kashaya Rasa* all have *Kapha* alleviating action. *Laghu, Ushna* & *Ruksha guna* helps in alleviation of *Kapha. Snigdha guna* helps in alleviation of *Vata. Vata-Kaphahara* property of most of the content alleviates both *Vata* and *Kapha*, which are the main *Doshas* in the pathogenesis. The main factor in this disease as in many other diseases is *Ama* and the *Deepana-Pachana* properties of *Pippali, Hritaki, Ghrit* will digest the *Ama. Sothahara Karma* of *Pippali* and *Hritaki* will neutralize the *Srotorodha* in *Pranavaha srotas* due to *Sotha* created by *Sama Vata*.*Vatanulomana* property (*Pippali* and *Haritaki*) maintains the normal flow of *Vata. Shwasa, Kasa Prabhava* (*Draksha*, *Karkatshringi, Pippali, Haritaki*) act on the symptoms. Honey has good *Kaphahara* action and *Yagavahi* property.

***Vasadi Syrup*:** It contains Vasa, Shunti, Kantkari, Guduchi and Sharkara. Majority of the ingredients have Tikta, Kashaya and Katu Rasa. Katu and Tikta Rasa drugs are known for its Deepana and Pachana properties. Due to Pachana properties the 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.

Comparison of effect of trial drug:
The effect of both the groups was found almost the same. An apparent difference of improvement in all the cardinal symptoms is observed in both the groups. The striking similarities in the results of both the groups may be due to the "*Pathyacharana",* which

is strictly followed as a part of treatment during the study. It shows the upper hand of *Pathyacharana* in the management of disease. On considering the above data it can be said that *Drakshadi avleha* and *Vasadi syrup* both give similar and highly significant results in the management of *Tamaka shwasa.*

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