A RANDOMIZED COMPARATIVE CLINICAL EVALUATION OF HARIDRADI LEHA AND VASADI KASHAYA IN THE MANAGEMENT OF TAMAKA SHWASA (BRONCHIAL ASTHMA)

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ABSTRACT

Tamaka Shwasa in Ayurveda is analogous to Bronchial Asthma due to similarity in causative and precipitating factors, onset, pathogenesis and symptoms. An estimated 300 million people worldwide suffer from asthma, with 250,000 annual deaths attributed to the disease. The Objective is to evaluate and compare the efficacy of Haridradi Leha with and without Vasadi Kashaya in the management of Tamaka Shwasa. Total 30 patients were registered for the present study. The patients of group A were administered Haridradi Leha in a dose of 20 grams BD (Bis in die i.e., twice daily) in empty stomach orally with lukewarm water for 21 days. The patients of group B were administered Haridradi Leha (20 grams BD) and Vasadi Kashaya (50 ml BD) with Anupana (co-administers with medicine) of honey orally for 21 days. There are highly significant results (p value: $p < 0.01$, $p < 0.001$) in breathlessness, cough, body position, wheezing in a day, wheezing in night, heart rate in both group but quantity of sputum, respiratory rate, use of accessory muscle and mental status shows highly significant result only in Group B. Both groups have highly significant result in peak expiratory flow rate (PEFR) and forced expiratory volume in one second (FEV₁). Both the Haridradi Leha and Vasadi Kashaya are highly effective in the management of Tamaka Shwasa. Haridradi Leha along with Vasadi Kashaya provided better relief than Haridradi Leha alone in most of the sign and symptom of the disease at significant level.

Keywords: Bronchial Asthma; Haridradi Leha; Tamaka Shwasa; Vasadi Kashaya.

INTRODUCTION

Shwasakashta (breathlessness, breathing difficulty) in Ayurveda is described as a presenting feature of Pranvaha sroto-dushti (disorders of Pranvaha Srotas). Charaka has described five types of Shwasa (asthma, respiratory disorders) viz Maha Shwasa, Urdhva Shwasa, Chinna Shwasa, Tamaka Shwasa and Kshudra Shwasa.¹ A type of Shwasa Roga in which patients feels excessive difficulty in breathing and drowning in dark is known as Tamaka Shwasa.² It is analogous to Bronchial asthma (BA) due to similarity in symptoms such as Asinolabhate Soukhyam (relaxed in sitting posture), Kasa (cough), Pratamyati Vegataha (Tachypnoea), Parshwa Graham (stiffness in flanks), Kanthodhwansa (hoarseness of voice), and other symptoms of Tamaka Shwasa are comparable to bronchial asthma symptoms. Bronchial asthma, a most common form of asthma, is a condition in which an individual's airways get inflamed, narrowed, and swollen, as well as generate excess mucus, making breathing difficult.

According to Global Strategy for Asthma Management and Prevention (2020 update) "Asthma is a heterogeneous disease, usually characterized by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and in intensity, together with variable expiratory airflow limitation. Airflow limitation may later become persistent."³

Asthma is one of the major non communicable diseases affecting 1-18% of the population in different countries.³ It was estimated that more than 339 million people had Asthma globally in 2016 and is common among children; there were 417,918 deaths due to asthma at the global level and 24.8 million disability adjusted

life years (DALYs) attributable to Asthma in 2016.⁴ According to The Global Asthma Report 2018, "among India's 1.31 billion people, about 6% of children and 2% of adults have asthma. Most people do not have health insurance and there is a wide gap in healthcare facilities for rich and poor".⁵ An estimated 300 million people worldwide suffer from asthma, with 250,000 annual deaths attributed to the disease. It is estimated that the number of people with asthma will grow by more than 100 million by 2025.⁶ Though, the incidence of this disease is increasing day by day, there is no satisfactory treatment available. Presently, the long-acting beta-adrenoceptor agonists, bronchodilators, mast cell stabilizer, leukotriene antagonists and corticosteroids are the mainstay in this condition however; they have serious adverse effects and have limitations for a long-term therapy. The immunosuppressive drugs are reserved for selected cases, while the disease modifying drugs like gold-salts, tacrolimus, sirolimus (rapamycin) are costly and have low benefit risk ratio. Hence, there is a need for drugs having good efficacy with low toxic profile in this critical disorder. A number of indigenous drugs have been claimed to be effective in the treatment of bronchial asthma but their claims have not been largely substantiated in well controlled clinical trials. Haridradi Leha and Vasadi Kashaya, are such preparations which has been described in the Ayurvedic Text.^{7,8} After reviewing the Ayurvedic and modern pharmacological properties and their role in Samprapti vighatan (breaking the pathogenesis), this formulation has been selected under the study. Thus, this study was performed to evaluate and compare the efficacy of Haridradi Leha with and without Vasadi Kashaya in the management of Tamaka Shwasa. This will explore the status about the role of Ayurvedic medicine in treatment of Bronchial asthma which may help scientific community to prepare treatment protocol.

MATERIALS AND METHODS

Study Design

This study was a single centric open label, randomized, interventional and comparative type.

Ethical clearance

This study is carried out as per international conference of harmonization-good clinical practices guidelines (ICH-GCP) or as per declaration of Helsinki guidelines. An informed written consent was taken from each patient willing to participate before the commencement of the trial. The patients were free to withdraw their name from the study at any time without giving any reason.

Selection of cases

In this study patients were registered in two groups from OPD & IPD of Kayachikitsa department, National Institute of Ayurveda by simple random sampling method.

In this study, patients were enrolled in two groups using a simple method of random sampling.

Duration of study

The treatment period was of 21 days. Patients were examined for the change in the signs and symptoms on 7th, 14th and 21st day of treatment.

Participants

Inclusion criteria

- Patients of either sex with age between 18 to 60 years.
- Patient present with moderate signs and symptoms of Tamaka Shwasa.
- Patient with stable bronchial asthma (as per WHO GINA Guideline) for at least 6 weeks prior to study entry.

Exclusion criteria

- Patients with mild and severe bronchial asthma.
- Patients present with co-morbid disorders like diabetes mellitus (DM), tuberculosis (TB), rheumatoid arthritis (RA), cancer (Ca), poorly controlled Hypertension, serious hepatic disorder or renal disorders, severe pulmonary dysfunction,
- Patients having alcohol dependence and hypersensitivity to the trial drug, Pregnancy or lactating women.

Withdrawal criteria

The criteria developed for withdrawal of participant was if

- He/ She develops any serious adverse effect (necessitating hospitalization)
- There is non-compliance of the treatment regimen (minimum 80% compliance) is essential to continue in the study)
- Patients himself wants to withdraw from the clinical trial.

Drug intervention

Total 30 patients were registered for the present study with 15 patients in each group.

Table 1: Mode of Administration of Drugs

<p>Group A (Haridradi Leha) Dose: 20 grams (Leha) Anupana: Luke warm water Route of administration: Oral Time of administration: Twice a day, in empty stomach Duration: 21 days</p>	<p>Group B (Haridradi Leha and Vasadi Kashaya) Dose: 20 grams (Leha) Anupana: Vasadi Kashaya along with honey Route of administration: Oral Time of administration: Twice a day, in empty stomach Duration: 21 days</p>
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Diagnostic criteria

A special Performa was prepared with all points of history taking, physical signs and laboratory investigations to confirm the diagnosis as mentioned in our classics as well as allied sciences. 30 patients with confirmed diagnosis of Tamaka Shwasa/ bronchial asthma fulfilling the diagnostic, inclusion, exclusion criteria were selected for the study.

Assessment criteria

The trial drugs' efficacy was assessed using a specific grading pattern based on the relief of cardinal signs and symptoms and specific pathological laboratory markers before and after treatment with the following subjective and objective parameters.

Subjective parameters

Subjective symptoms like cough, breathlessness, sputum, speech, respiratory rate, heart rate, wheezing at day, wheezing in night, etc. was scored using a specific grading pattern based on the relief of cardinal signs and symptoms before and after the treatment (Table 2).

Objective parameters

For the purpose of diagnosis of a disease its assessment, severity, clinical improvement and to assess the possible side effects, certain routine and specific investigations were performed in every patient viz.

Investigations

- Haematology: Haemoglobin (Hb), total leucocyte count (TLC), differential leucocyte count (DLC), erythrocyte sedimentation rate (ESR), absolute eosinophil count (TEC) and fasting blood sugar (FBS).
- Bio-chemistry: serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT), blood urea and serum creatinine.
- Spirometry: peak expiratory flow rate (PEFR) and forced expiratory volume in one second (FEV₁).

Following investigations were done to exclude various cardiac & pulmonary disorders.

- X-Ray chest - PA view
- ECG

Table 2: Assessment Grading Scale

1. Shortness of breath/ breathlessness	Grade
Can walk indefinitely	1
Short breath by strenuous work	2
Short breath by moderate work (by climbing 1-2 stairs)	3
Short breath by minimum work (by climbing 1 stair)	4
Shortness of breath at rest	5
2. Grading for Cough	Grade
No cough	1
Occasional cough but not disturbing	2
Cough troublesome during attacks	3
Cough very troublesome & Frequent	4
Cough distressing most of the time Day/Night	5
3. Quantity of Sputum	Grade
Nil	0
Less than 2.5 ml per day	1
Ranging from 2.5 ml to 10 ml	2
More than 10 ml per day	3
4. Respiratory rate	Grade
Less than or equal to 30 breath/min	1
Ranging from 31 to 45 breath/min	2
Ranging from 46 to 60 breath/min	3
More than 60 breath/min	4
5. Body position	Grade
Normal	0
Able to recline	1
Prefers sitting	2
Unable to recline	3
6. Wheezing at day	Grade
No discomfort	1
Once a while in day	2
Twice a day	3
Three to Four times a day	4
More than five times a day	5
7. Wheezing at night –	Grade
Sleep throughout night	1
Awakened once	2
Awakened twice	3
Awakened three to four times	4
Awakened almost one hourly	5
8. Use of accessory muscle	Grade
None	0
Mild	1
Moderate	2
Marked	3
9. Grading for Speech	Grade
Speech Possible	0
Speech difficulty	1
10. Heart rate	Grade
Normal (72/min)	0
Mild (100/min)	1
Moderate (100-110/min)	2
Severe (> 120/min)	3
Impending respiratory failure Relative bradycardia	4
11. Mental status	Grade
Normal	0
Agitated	1
Depressed	2
Coma	3
12. PEF	Grade
Range from 350-500 litre per min	0
Range from 250-350 litre per min	1
Range from 150-250 litre per min	2
Range from 150 litre per min & below	3
13. FEV ₁	Grade
FEV ₁	Pre-bronchodilator predicted > 95%
	95-90%
	89-80%
	79-70%
	69-60%
	59-50%
	< 50%

Statistical Analysis

The information gathered on the basis of observation made about various parameters was subjected to statistical analysis in terms of Mean, Standard Deviation and Standard error (SE). In Stat Graph Pad software was used & For non-parametric data Wilcoxon matched-pairs signed ranks test was used while for parametric data Paired 't' test was used and results were calculated. Paired 't' test was carried out at $p < 0.05$, $p < 0.01$, $p < 0.001$. For intergroup comparisons, for the

nonparametric variables we used Mann-Whitney Test for statically analysis and for the parametric data, we used Unpaired t test. The results were calculated.

Insignificant: $p > 0.05$

Significant: $p < 0.05$

Highly significant: $p < 0.01$, $p < 0.001$, $p < 0.0001$.

Figure 1: Consort flow chart of study

RESULTS

A total of 30 patients participated in the study. No patients in either group reported any adverse effects. No patient dropped out in the study. (Figure 1)

In the present study maximum number of patients (63%) were in the age group of 18-30 years, male and female ratio was equal, 50% were belonged to lower socio-economic status, 57% of patients were doing desk work, 50% patients were belonging to urban habitat, 63% patients reported disturbed sleep, maximum patients (83%) had no association with family history, 64% patients were of normal weight (BMI noticed between 18.50 to 24.99), 50% patients were suffering from moderate stress. Maximum patients i.e., 73.33% were doing Vishamashana

(irregular diet), 43% had Krura Koshtha (irregular nature of bowel), 47% of patients were having Vishamagni (irregular state of agni), 52.5% were having past history of allergy.

It was found that maximum patients had Aharaaja Nidana (dietary causative factor) as Dadhi Sevana (Curd intake- 83.33%) and Sheeta-Ushna Saha Sevana (intake of cold and hot food together- 83.33%), Vidahi (food that produces burning sensation-73.33%), Vishamashana (73.33%), Sheeta Ambu Pana (cold water- 76.66%), Adhyashana (over eating- 63.33%), 73% were taking Madhura Rasa (sweet taste) dominant diet. In Viharaja Nidanas (lifestyle causative factor), maximum 76.66% patients were exposed to Raja (dust). Dhuma (fumes) exposure was found in 63.33% and 50% each from Sheeta Sthana (residing in cold), & Diwaswapna (day sleep). In this study 33% of patients were of

patients were reported with Vata-Kaphaja Prakriti, while 70% patients having history of rhinitis, 87% patients were having allergy to some material. 63% patients were allergic to dust.

Cardinal symptoms

According to the data of this clinical study, it observed that Shwasakashtata (breathlessness) was present in 100% patients, Kasa (cough) was present in 63.33%, Pinasa (catarrh) was present in 70%, Parshva Shula was observed in 36.66%, while Kapha Nishthivanam (expectoration of sputum) was present in 80% patients.

Associated symptoms

Trisha (thirst) was reported by 30% patients and Vibandha (constipation) was observed in 70% patients and Kanthodhwansa (inflammation of throat, hoarseness of voice) was found in 40% patients as associated symptoms. Likewise, Krichchherna Bhasitum (difficult to speak) was reported by 40% patients, Lalate Sweda (sweating on forehead) was observed in 26.66% each, Vishushkasyata (dryness of mouth) was found in 56.6% and Pramoha (severe confusion) was observed in 10% patients as associated symptoms during attack.

Results in the patients of Group A

In Group A, patients were treated with Haridradi Leha with lukewarm water, showed highly significant results ($p < 0.01$, $p < 0.001$) for subjective parameters- breathlessness, cough, body position, wheezing in a day, wheezing in night, heart rate with relief of 43.90%, 37.49%, 56.26%, 44.11%, 31.26%, 54.17% respectively. For other Subjective parameters i.e., quantity of sputum, respiratory rate, mental status showed significant result ($p < 0.05$) with relief of 36.35%, 33.33%, 47.07%. There were no significant result in other subjective parameters i.e., use of accessory muscle and speech. (Table 3, Graph 1 and Graph 3)

Objective parameters, PEFR and FEV_1 showed highly significant result ($p < 0.01$) with 45.44% and 33.33% improvement respectively. Hemoglobin, SGOT, Blood urea have shown significant ($p < 0.05$) result with improvement of 3.376%, 15.64%, 11.44% respectively, while ESR, TEC, FBS, SGPT, Serum creatinine have shown no significant result. (Table 4, Graph 2 and Graph 4)

Results in the patients of Group B

The treatment with Haridradi Leha and Vasadi Kashaya showed highly significant results ($p < 0.01$, $p < 0.001$) for subjective parameters- breathlessness, cough, quantity of sputum, respiratory rate, body position, wheezing in a day, wheezing in night, use of accessory muscle, heart rate, mental status with relief of 48.77%, 46.15%, 51.85%, 40.74%, 66.65%, 45.93%, 38.88%, 55.01%, 58.33%, 47.35% respectively. While, speech had non-significant result. (Table 3, Graph 1 and Graph 3)

Objective parameters, PEFR, FEV_1 , have shown highly significant result ($p < 0.01$) with 68.40%, 46.66% improvement respectively. SGOT, SGPT have shown significant result while HB, ESR, TEC, FBS, Blood urea, Serum creatinine have shown non-significant result. (Table 3, Graph 2 and Graph 4)

Intergroup Comparison

Intergroup comparison of both groups showed statistically non-significant results ($p > 0.05$) which means that there is no statistical difference in efficacy of both treatments on all subjective and objective parameters. (Table 3 and Table 4) But, Haridradi Leha & Vasadi Kashaya provided better relief in most of the signs and symptoms of the disease than Haridradi Leha alone.

Safety Profile

Liver function parameters (SGOT, SGPT) and renal function parameters (blood urea, serum creatinine) were within normal limit before and after treatment. No adverse drug reaction was observed in any of the groups throughout the study.

DISCUSSION

Tamaka Shwasa is considered to be Kapha-Vataja dominant disease which originates from Pitta Sthana (receptacle for Pitta). Whenever due to responsible causative factors Kapha aggravates, it causes obstruction of Srotas (structural or functional channels), Pranvaha Srotas (channels of respiration) in particular. Srotas obstruction further aggravates the vitiated Vata and attains Pratiloma Gati (reverse movement) and thus establishes the pathogenesis of Tamaka Shwasa, obstruction of Pranvaha srotas by Kapha Dosha and Pratiloma gati of Vata Dosha are hallmarks in the pathogenesis of Tamaka Shwasa.²

The key purpose of treatment in Ayurveda is to attain Samyata (equilibrium) of vitiated Dosha for which various Shodhana (bio-cleansing therapy) and Shamana (alleviating therapy) therapies are described. For Tamaka Shwasa, though Shodhana is better than Shamana, but it cannot be applied in every individual due to various status of Dosha as well as physical status of the patients.⁹ In the classics also, the Shamana therapy has been considered essential then Shodhana and before Brimhana (nourishing) therapy for the treatment of Tamaka Shwasa.¹⁰ In Ayurveda, Chakrapani Datta has advocated Kapha-Vatahara (Kapha and Vata relieving) and Vatanulomana (proper functioning of Vayu) Chikitsa as line of treatment of Shwasa roga.¹⁰

These formulations under trial i.e., Haridradi Leha and Vasadi Kashaya help in breaking the pathology of Tamaka Shwasa in which Vata and Kapha are the two key pathological factors involved. According to Vagbhata, drug acts by its Rasa (elemental character responsible for taste), Vipaka (bio-transformed Rasa), Veerya (potency), Guna (property) and Prabhava (exceptional activity).¹¹ Normally effect of Rasa is less than that of Vipaka. Effect of Vipaka is less than that of Veerya, which further is less than effect of Prabhava, provided all are present equal proportions.¹² Specifically the properties like Katu Rasa and Ushna Veerya, Laghu Tikshna and Ruksha quality of Haridra (*Curcuma longa*), Maricha (*Piper nigrum*), Pippali (*Piper longum*), Rasna (*Pluchea lanceolata*) etc. alleviates Kapha and Ushna Veerya, Snigdha Guna of Guda and Mustard oil pacifies Vata Dosha.^{13,14} Thus Kapha Shamaka properties of drug help in breaking the Shrotorodha and digestion of Ama, which leads to proper functioning of the body. Tikta Rasa boost Jatharagni and helps to complete the Pachana of Ama Dosha.¹⁴ This property controls the initial Ama formation, if formed in any way it can be neutralized which is vital in preventing the disease. Katu Rasa reduces Kapha and Vata due to its Ushna, Tikshna, Vishada (conspicuousness) Guna. Vishada Guna helps in absorption of Kleda (moistness). Katu Rasa also has Deepana (digestion and metabolism enhancing), Pachana (digestion), and Sroto Prakashaka action.¹³

Table 3: Effect of Intervention over Subjective Parameters

Subjective Parameters	Group	Showing effect of therapy (WMPSR test)							Inter group comparison (Mann-Whitney Test)				
		Mean		Mean Diff.	SD±	SE±	p	S	Mean diff.	SD±	SE±	p	S
		BT	AT										
Breathlessness	A	2.733	1.533	1.200	0.4140	0.1069	< 0.0001	HS	1.533	0.5164	0.1333	> 0.05	NS
	B	2.733	1.400	1.333	0.4880	0.1260	< 0.0001	HS	1.400	0.6325	0.1633	> 0.05	NS
Cough	A	2.667	1.667	1.000	0.3780	0.0976	< 0.0001	HS	1.667	0.7237	0.1869	> 0.05	NS
	B	2.600	1.400	1.200	0.7746	0.2000	< 0.001	HS	1.400	0.6325	0.1633	> 0.05	NS
Quantity of sputum	A	1.467	0.9333	0.5333	0.7432	0.1919	< 0.05	S	0.9333	0.7037	0.1817	> 0.05	NS
	B	1.800	0.8667	0.9333	0.4577	0.1182	< 0.001	HS	0.8667	0.7432	0.1919	> 0.05	NS
Respiratory Rate	A	1.600	1.067	0.5333	0.6399	0.1652	< 0.05	S	1.067	0.2582	0.06667	> 0.05	NS
	B	1.800	1.067	0.7333	0.7037	0.1817	< 0.001	HS	1.067	0.2582	0.06667	> 0.05	NS
Body position	A	2.133	0.9333	1.200	0.5606	0.1447	< 0.001	HS	0.9333	0.8837	0.2282	> 0.05	NS
	B	2.000	0.6667	1.333	0.4880	0.1260	< 0.001	HS	0.6667	0.7237	0.1869	> 0.05	NS
Wheezing in day	A	2.267	1.267	1.000	0.8452	0.2182	< 0.001	HS	1.267	0.7037	0.1817	> 0.05	NS
	B	2.467	1.333	1.133	0.8338	0.2153	< 0.001	HS	1.333	0.8165	0.2108	> 0.05	NS
Wheezing in night	A	2.133	1.467	0.6667	0.4880	0.1260	< 0.001	HS	1.467	0.5164	0.1333	> 0.05	NS
	B	2.400	1.467	0.9333	0.4577	0.1182	< 0.001	HS	1.467	0.6399	0.1652	> 0.05	NS
Use of Accessory muscle	A	1.000	0.8000	0.2000	0.5606	0.1447	> 0.05	NS	0.8000	0.6761	0.1746	> 0.05	NS
	B	1.333	0.6000	0.7333	0.4577	0.1182	< 0.001	HS	0.6000	0.6325	0.1633	> 0.05	NS
Speech	A	0.5333	0.2667	0.2667	0.5936	0.1533	> 0.05	NS	0.2667	0.4577	0.1182	> 0.05	NS
	B	0.6667	0.3333	0.3333	0.6172	0.1594	> 0.05	NS	0.3333	0.4880	0.1260	> 0.05	NS
Heart Rate	A	1.600	0.7333	0.8667	0.5164	0.1333	< 0.001	HS	0.7333	0.7037	0.1817	> 0.05	NS
	B	1.600	0.6667	0.9333	0.2582	0.06667	< 0.001	HS	0.6667	0.6172	0.1594	> 0.05	NS
Mental status	A	1.133	0.6000	0.5333	0.6399	0.1652	< 0.05	S	0.6000	0.5071	0.1309	> 0.05	NS
	B	1.267	0.6667	0.6000	0.5071	0.1309	< 0.001	HS	0.6667	0.6172	0.1594	> 0.05	NS

WMPSR test- Wilcoxon matched paired single ranked test, MW test- Mann-Whitney Test, HS – Highly significant, S – Significant, NS – Not significant, BT: Before Treatment, AT: After Treatment

Table 4: Effect of Intervention over Objective Parameters

Objective Parameter	Group	Showing effect of therapy (Paired 't' Test)								Intergroup comparison (Unpaired t Test)					
		Mean		Diff	SD±	SE±	T	p	S	Mean	SD±	SE±	t value	p	S
		BT	AT												
PEFR	A	1.467	0.8000	0.6667	0.7237	0.1869	3.568	< 0.001	HS	0.8000	0.7746	0.2000	1.673	> 0.05	NS
	B	1.267	0.4000	0.8667	0.5164	0.1333	6.500	< 0.001	HS	0.4000	0.5071	0.1309			
FEV ₁	A	2.800	1.867	0.9333	0.5936	0.1533	6.089	< 0.001	HS	1.867	0.6399	0.1652	1.265	> 0.05	NS
	B	3.000	1.600	1.400	0.5071	0.1309	10.693	< 0.001	HS	1.600	0.5071	0.1309			
Hb	A	11.847	12.247	0.4000	0.6803	0.1757	2.277	< 0.05	S	12.247	1.324	0.3420	0.08535	> 0.05	NS
	B	11.907	12.200	0.2933	0.8681	0.2241	1.309	> 0.05	NS	12.200	1.652	0.4266			
ESR	A	14.400	13.680	0.7200	7.845	2.026	0.3554	> 0.05	NS	13.680	9.064	2.340	1.540	> 0.05	NS
	B	10.800	9.600	1.200	2.597	0.6705	1.790	> 0.05	NS	9.600	4.808	1.241			
TEC	A	280.60	249.40	31.200	143.95	37.167	0.8394	> 0.05	NS	249.40	114.29	29.510	0.3325	> 0.05	NS
	B	315.80	273.13	42.667	276.24	71.324	0.5982	> 0.05	NS	273.13	251.74	64.999			
FBS	A	96.467	90.467	6.000	17.312	4.470	1.342	> 0.05	NS	90.467	16.496	4.259	0.1462	> 0.05	NS
	B	95.133	91.200	3.933	7.526	1.943	2.024	> 0.05	NS	91.200	10.248	2.646			
SGOT	A	37.147	31.333	5.813	9.145	2.361	2.462	< 0.05	S	31.333	7.403	1.912	0.3194	> 0.05	NS
	B	41.533	30.600	10.933	15.741	4.064	2.690	< 0.05	S	30.600	4.925	1.272			
SGPT	A	34.067	25.933	8.133	15.556	4.016	2.025	> 0.05	NS	25.933	6.100	1.575	1.337	> 0.05	NS
	B	40.067	29.667	10.400	17.948	4.634	2.244	< 0.05	S	29.667	8.934	2.307			
Blood urea	A	31.467	27.867	3.600	5.082	1.312	2.743	< 0.05	S	27.867	3.543	0.9148	1.196	> 0.05	NS
	B	31.267	29.933	1.333	7.961	2.056	0.6486	> 0.05	NS	29.933	5.675	1.465			
Serum creatinine	A	1.093	0.9067	0.1867	0.3461	0.08937	2.089	> 0.05	NS	0.9067	0.1280	0.03305	0.08934	> 0.05	NS
	B	1.013	0.9000	0.1133	0.3852	0.09946	1.139	> 0.05	NS	0.9000	0.2591	0.06690			

PEFR – Peak expiratory flow rate, FEV₁ – Forced expiratory volume in one sec., HB – Haemoglobin, ESR – Erythrocyte Sedimentation Rate, TEC – Total Eosinophil Count, FBS – Fasting Blood Sugar, SGOT – Serum Glutamic Oxaloacetic Transaminase, SGPT – Serum Glutamic Pyruvic Transaminase, BT: Before Treatment, AT: After Treatment

Graph 1: Effect of therapy (Subjective Parameters)

Graph 2: Effect of therapy (Objective Parameters)

Graph 3: Percentage relief in both the groups in Subjective Parameters

Graph 4: Percentage relief in both the groups in Objective Parameters

Draksha & Guda help in nourishment of Rasa Dhatu; which mainly used to be vitiated in Tamaka Shwasa. Some ingredients of study drugs have Rasayana Prabhava (Pippali and Guduchi). The Rasayana drug are supposed to increase both qualitatively and quantitatively improvement of all Dhatus of the body. Thus, both the formulation has role of Deepana, Pachana, Strotoshodhana (cleansing of channels), Shothahara (reduces inflammation) Vatanulomana, Vata-Kaphaghna and Rasayana properties.

On the basis of modern pharmacology these medicines exhibit expectorant, anti-inflammatory, antispasmodic, bronchodilator, anti-allergic, antibacterial, respiratory stimulant and immunomodulatory properties. In contemporary parlance, the pharmacological role of these drugs as IgE neutralisation, inflammation & bronchial hyper-reactivity suppression, Blockade of constrictor neurotransmitter mast cell stabilizers, leukotriene receptor antagonist, anti-oxidant and bronchodilator demonstrates their efficacy with the key factors.¹⁵ The suppression of inflammation and bronchial hyper-reactivity of Haridra, Pippali (*Piper longum*), Rasna and honey plays a vital role to make the formulations effective. Curcumin of Haridra

helps to inhibit a variety of different molecules involved in inflammation, degranulation and to suppress histamine release, Rasna has immune suppressing effect which ultimately neutralizes immunoglobulin E.¹⁶⁻¹⁸ Piper extracts suppress histamine, interleukin-5, immunoglobulin E and interleukin-4 production exhibits anti-inflammatory action.^{19,20} Vasa (*Adhatoda vasica*), Shati (*Hedychium spicatum*), Kantakari (*Solanum xanthocarpum*), Amrita (*Tinospora cordifolia*), and Honey also shows antihistaminic and anti-inflammatory effects, with Kantakari acting as a leucotriene antagonist.^{21,22} Anti-cholinergic properties are found in Shati and Vasa.^{23,24} Shati, Vasa, Kantakari exhibits bronchodilator effect.²⁵⁻²⁷

Both groups showed highly significant results regarding subjective parameters like breathlessness, cough, body position, wheezing in a day, wheezing in night, and heart rate. But the parameters like quantity of sputum, respiratory rate, use of accessory muscle and mental status are significantly relieved in only Group B. While interpreting the effect of medicines over objective parameters, both groups showed highly significant result in PEFR and FEV₁. Group A showed significant result in Haemoglobin, SGOT and Blood urea only whereas SGOT and

SGPT only in Group B. This shows that both formulations are highly effective but the Kashaya along with Leha has synergistic role in treatment of Tamaka shwasa.

CONCLUSION

Both the Haridradi Leha and Vasadi Kashaya are highly effective in the management of Tamaka Shwasa. Finally on comparing the effect of two therapies, though seems no any difference statistical tests, it can be concluded that Haridradi Leha and Vasadi Kashaya provided better relief than Haridradi Leha alone in most of the sign and symptom of the disease at significant level.

Limitations and Recommendation for future studies

The study under report was a time bound short-term trial and had many limitations; relatively little number of patients in each sub group had been one of them.

Hence it is suggested that an extended clinical trial should be undertaken to evaluate the definite role of the drug and its side effects, if any with following recommendations

- The duration of the therapy should be at least 3 months to seek the expected results for Shaman therapy.
- Study may be conducted on same drug with large sample size.
- In both the group subdivision should be done on the basis of Samprapti.
- Estimation of serum IgE level should be done before and after treatment to prove its efficacy on immune system.
- Scoring criteria needs more specificity.

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