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Efficacy of *Vasa Avaleha* and its granules on *Tamaka Shwasa* (bronchial asthma): Open-label randomized clinical study

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Abstract

Introduction: Bronchial asthma is one of the chronic inflammatory disorders of the respiratory tract causing a huge number of deaths annually. Increased industrialization and pollution are the exacerbating factors for this situation. In Ayurveda, this miserable condition is comparable with *Tamaka Shwasa*. Synthetic drugs provide instant symptomatic relief in cases of bronchial asthma but are known to develop certain adverse drug reactions. Considering this, the current suffering population is looking hopefully towards other systems of medicine such as Ayurveda for better relief. Ayurveda has a number of formulations to treat *Tamaka Shwasa* and is in practice with proven efficacy. **Aims:** To evaluate comparative clinical efficacy of *Vasa Avaleha* (VA) and its granules (GVA) in cases of *Tamaka Shwasa*. **Materials and Methods:** A total of 66 patients were registered and randomly grouped into A and B. Patients of Group A were treated with VA, while Group B with GVA at dose of 6 g twice a day with lukewarm water for the duration of 28 days. Follow-up was done after 14 days. The results were assessed in terms of clinical recovery, symptomatic relief, and pulmonary function improvement. Effect of the treatment was assessed based on subjective and objective parameters. **Results:** Significant improvement was observed in most of the cardinal and associated symptoms. Significant increase in peak expiratory flow rate, considerable decrease in absolute eosinophil count, and increased breath holding time were noticed. Withdrawal of modern emergency drugs, decreased frequency of attacks, improved quality of life were the major observations noticed in both groups. **Conclusions:** This study highlights the significance of traditional herbal formulations in noncommunicable diseases such as bronchial asthma, which can be used as an effective drug in place or along with modern drugs.

Key words: Bronchial asthma, noncommunicable disease, *Tamaka Shwasa*, *Vasa Avaleha*

Introduction

Asthma is one of the most common chronic diseases. An estimated 300 million people worldwide suffer from asthma, with 250,000 annual deaths attributed to the disease.[1] The prevalence of asthma in different countries varies widely, but the disparity is narrowing due to rising prevalence in low- and middle-income countries and plateauing in high-income countries.[2] Increased rate of its prevalence may be because of changes in life-style, rapid industrialization, increase in air pollution etc. Common risk factors of asthma include exposure to allergens (such as those for work place, house dust, mites, animal fur, cockroaches, pollens, and mold), occupational irritants,[1] tobacco smoke,[3] respiratory infections, food allergies (such as milk, peanuts, and eggs), and psychological stress.[4] During asthma attack, the lining of the bronchial tubes

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swell, causing the airways to narrow and reducing the flow of air into and out of the lungs causing sleeplessness, daytime fatigue, reduced activity levels and school and work absenteeism.[5] This miserable condition is comparable to *Tamaka Shwasa* in Ayurveda.

Detailed description of *Tamaka Shwasa* including pathogenesis, signs and symptoms, and treatment is available in Ayurveda classics.[6] The symptoms of *Tamaka Shwasa* are *Asinolabhate Soukhyam* (comfortable in sitting posture), *Pratamyati Vegataha* (tachypnea), *Kasa* (cough), *Kanthodhwansa* (hoarseness of voice), *Parshwa Graham* (stiffness in flanks), etc., and are similar to the symptoms of bronchial asthma. Although modern system of medicine has their own lines of treatment for this condition, they are known to develop various adverse reactions. Observing all these, the scenario is hopefully looking toward traditional systems of medicine such as Ayurveda for better answers.

Vasa Avaleha (VA) is herbal formulation used commonly in the treatment of various diseases of respiratory system.[7] In the current study, it has been planned to evaluate comparative clinical efficacy of VA and its granules (GVA) in *Tamaka Shwasa*.

Materials and Methods

Patients of both sex, between the age of 12 and 70 years with mild persistent cases of bronchial asthma, were registered in the trial from outdoor and indoor patient department IPGT and RA Hospital, Jamnagar. The study obtained Institutional Ethics Committee clearance (PGT/7-A/2012-2013/1964/22 dated 21/09/2012) and registered at Clinical Trial Registry of India (CTRI/2012/12/003184). A written informed consent from each patient was taken before enrolling in the clinical trial.

Exclusion criteria

Dyspnea resulting from other diseases such as left ventricular failure, chronic obstructive pulmonary disease (chronic bronchitis, emphysema), upper respiratory tract obstruction, patients with anemia, pneumonia, tuberculosis, lung cancer, lung abscess, and other such complicated conditions were excluded from the study.

Investigations

Routine hematological, especially white blood cell, erythrocyte sedimentation rate, absolute eosinophil count (AEC), and urine examination were carried out in all the patients. Biochemical investigations such as random blood sugar, serum glutamic pyruvic transaminase, serum glutamic oxaloacetic transaminase, and chest X-ray were carried out as per the need to exclude other pathologies. Breath holding time (BHT) and peak expiratory flow rate (PEFR) were also recorded in all the patients before and after treatment.

Diet and restrictions

Patients were advised to avoid cause and aggravating factors such as curd, cold drinks, fish and meat, tobacco chewing and smoking, alcohol, excessive physical work, day sleep, and exposure to dust, smoke, pets, and pollens. Patients were advised to use lukewarm water after meal and at bed time. They were also advised for light diet, breathing exercises such as *Pranayama*, use of mask while working, to avoid exposure to dust and smoke, etc.

Trial drugs

The raw material was procured from Pharmacy, Gujarat Ayurved University, Jamnagar and authenticated in the Pharmacognosy Laboratory, IPGT and RA, Jamnagar. Both trial drugs were prepared in the Department of Rasashastra and Bhaishajya Kalpana, IPGT and RA, Jamnagar by following classical guidelines. Formulation composition of both trial drugs that is VA and GVA is shown in Table 1.

Grouping and posology

A total of 66 patients were randomly grouped into A and B using computer generated randomization [Chart 1], Group A (n = 32) received VA, while Group B (n = 34) received GVA at dose of 6 g twice a day with lukewarm water in the morning and evening for the duration of 28 days. Follow-up period was 14 days in both groups.

Criteria for assessment

Efficacy of the trial drugs was analyzed by specific grading pattern including asthma control questionnaire (ACQ) and asthma control test (ACT)[8-10] in terms of relief observed in cardinal signs and symptoms before and after treatment. Changes in PEFR, BHT, and AEC were also considered in evaluating comparative efficacy of the trial drugs.

Statistical analysis

Obtained data were statistically analyzed using Wilcoxon signed rank test, Paired t-test, Unpaired t-test, and Chi-square test.

Observations and Results

It was observed that 51.51% patients were of *Vata-Kapha Prakriti* followed by *Vata-Pitta Prakriti* (30.30%) and *Pitta-Kapha Prakriti* (18.18%). About 7.57% of patients registered in the study were addicted to tobacco smoking. Chronicity of 1–5 years duration was reported in 33.33% patients.

Effect of therapy on cardinal symptoms

Statistically highly significant results were observed in all the cardinal symptoms. Group A showed better improvement than Group B in breathlessness, frequency and intensity of attack and cough whereas in Group B, better effect on duration of attack, wheezing, tachypnea and night symptoms was found [Table 2]. The difference between the groups was statistically insignificant [Table 3].

Table 1: Formulation composition of *Vasa Avaleha* and Granules of *Vasa Avaleha*

Composition	Botanical/ English name	Part used	Proportion (part)	
			VA	GVA
Vasa	*Adhatoda vasica* Nees.	Leaf	1	1
Sharkara	Sugar candy	-	½	1
Go-Ghrita	Clarified butter	-	1/8	1/8
Pippali	*Piper longum* Linn.	Fruit	1/8	1/8
Madhu	Honey	-	½	1/10

VA: *Vasa Avaleha*, GVA: Granules of *Vasa Avaleha*

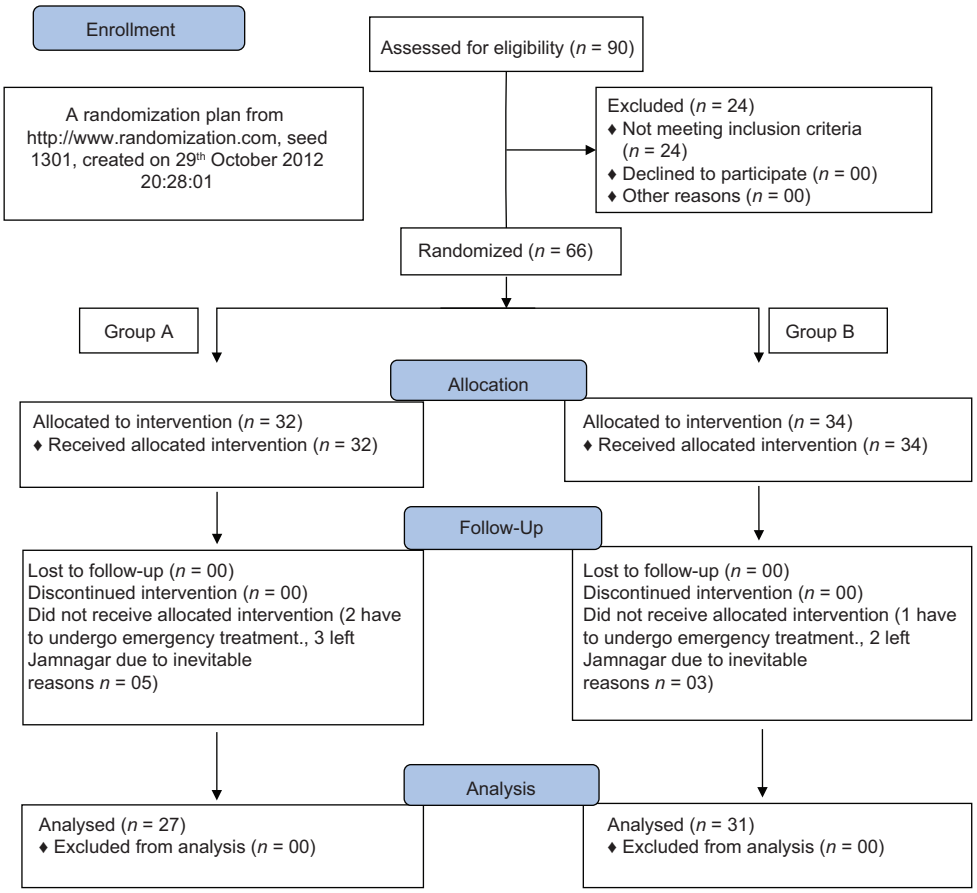

Chart 1: CONSORT flow diagram

Effect of therapy on associated symptoms

Effect of both trail drugs on associated symptoms was also highly significant except dryness of oral cavity in Group B [Table 4].

Effect of therapy on objective parameters

Effect of both trail drugs on objective parameters such as need of any reliever, BHT, and PEFR was statistically highly significant [Table 5]. ACT showed highly significant results in both groups whereas ACQ showed significant results in both groups [Table 6].

Overall effect of therapy

Complete remission was not found with any of the drugs. At the end of treatment, moderate improvement was found in 25.93% patients in Group A while 32.26% in Group B; mild improvement was found in 66.67% in Group A while 64.52% in Group B.

Discussion

Ayurveda emphasizes on *Srotorodha* (obstruction of channels) in the manifestation of *Shwasa Roga*, which is the resultant of disturbance in the equilibrium of *Vata* and *Kapha*. Hence, drugs that are beneficial in removing the obstruction and maintain the physiological equilibrium of *Vata* and *Kapha* are useful in pacifying *Tamaka Shwasa*. *Acharyas* have also provided specific guidelines in the management of *Tamaka Shwasa* with drugs having *Vata-Kapha Hara*, *Ushna*, and *Vatanulomana* properties.[11]

VA, an herbal formulation indicated in respiratory diseases, acts on the disease by *Vata-Kaphaghna* property. *Sukshma* and *Tikshna Guna* of *Vasa* (*Adhatoda vasica* Nees.), *Pippali* (*Piper longum* Linn.), *Madhu* (honey) help in *Kaphanihsarana* and remove *Upalepa* of *Kapha* in *Kantha* (throat) and *Ura* (chest). *Vatahara* drugs such as *Sita*, *Go-Ghrita* (cow ghee), *Pippali* cause *Vatanulomana* and passify *Vimarga Kupita Vata* caused due to *Vimargagami Prana* and *Apana Vayu*. *Go-Ghrita*, *Pippali* also act on *Pitta Sthana* improving the function of *Agni* thus normalizing *Vatakarma*. This process sets right the digestion, assimilation, and metabolism. Further, *Go-Ghrita*[12] and *Pippali* help in improving immunity of the body with their *Rasayana* (rejuvinative) effect, thus preventing the recurrences of symptoms.

Vasa, a major component of VA, is indicated in diseases such as *Shwasa*, *Rajayakshma* (tuberculosis), *Raktapitta*, *Shotha* (edema), and *Jwara* (fever).[13] Vasicine and vasicinone, the bitter alkaloids available in the plant, has bronco-dilatory effect. Few studies have proven 6–10 times greater efficacy of vasicinone against aminophylline in cases of bronchial asthma.[14]

Pippali enhances bioavailability,[15] which helps in maintaining the major therapeutic principles in the systemic circulation for longer duration that is responsible for the anti-asthmatic activity of the formulation.

Statistically highly significant ($P < 0.001$) results were obtained in both groups on cardinal symptoms such as breathlessness, paroxysm of breathlessness, intensity of the

Table 2: Effect of *Vasa Avaleha* and Granules of *Vasa Avaleha* on chief complaints

Symptoms	*n*	Mean±SEM		Change		Actual rank (*D*)	α
		Before time	After time	Mean±SEM	Percentage		
Breathlessness							
Group A	27	2.741±0.114	0.592±0.0133	2.1480.148	78.37↓	378	<0.0001
Group B	31	2.889±0.087	0.5833±0.115	2.3060.111	62.55↓	666	<0.0001
Frequency of attack							
Group A	20	3.500±0.305	1.150±0.208	2.3500.195	67.14↓	210	<0.0001
Group B	29	3.069±0.242	0.724±0.163	2.3450.15	51.30↓	406	<0.0001
Intensity of attack							
Group A	15	1.333±0.126	0.200±0.106	1.1330.090	84.99↓	120	<0.0001
Group B	18	1.389±0.118	0.333±0.114	1.0560.055	76.02↓	171	<0.0001
Duration of attack							
Group A	12	1.333±0.142	0.583±0.148	0.7500.130	56.26↓	45	<0.001
Group B	10	1.00±0.00	0.6±0.163	1.560.08	100↓	-	<0.001
Paroxysm							
Group A	27	2.407±0.110	0.370±0.142	2.0370.172	84.63↓	373	<0.0001
Group B	31	2.226±0.100	0.354±0.098	1.8710.111	84.05↓	496	<0.0001
Tachypnea							
Group A	6	1.833±0.307	0.500±0.341	1.3330.421	72.72↓	15	<0.05
Group B	13	2.154±0.104	0.384±0.140	1.7690.166	82.13↓	91	<0.0001
Wheezing							
Group A	27	2.519±0.123	0.555±0.123	1.9630.125	77.93↓	378	<0.0001
Group B	30	2.633±0.131	0.433±0.092	2.2000.139	83.55↓	465	<0.0001
Cough							
Group A	26	2.654±0.146	0.307±0.133	2.3460.183	88.39↓	325	<0.0001
Group B	30	2.633±0.131	0.466±0.104	2.1670.144	82.30↓	465	<0.0001
Chest tightness							
Group A	9	2.00±0.00	0.33±0.166	-	-	-	<0.0001
Group B	6	2.166±0.166	0.00±0.00	-	-	-	<0.0001
Relief after expectoration							
Group A	8	2.250±0.250	0.500±0.267	1.7500.313	77.78↓	28	<0.01
Group B	13	1.923±0.136	0.153±0.104	1.7690.166	91.99↓	91	<0.0001
Nasal symptoms							
Group A	12	2.167±0.166	0.416±0.193	1.7500.179	80.76↓	78	<0.001
Group B	20	2.000±0.072	0.400±0.112	1.6000.133	80.0↓	210	<0.0001
Night breathlessness							
Group A	10	1.800±0.133	0.600±0.221	1.2000.249	66.67↓	36	<0.01
Group B	15	1.933±0.248	0.266±0.118	1.6670.303	86.23↓	91	<0.0001
Night wheezing							
Group A	4	1.750±0.250	1.250±0.478	0.5000.500	28.57↓	1	>0.05
Group B	10	2.200±0.416	0.100±0.100	2.1000.433	95.45↓	55	<0.001
Awaking at night							
Group A	19	1.737±0.103	0.315±0.196	1.4210.139	81.81↓	171	<0.0001
Group B	26	1.615±0.136	1.153±0.072	1.4620.159	90.53↓	300	<0.0001

↓: Decrease, SEM: Standard error of mean

attack, frequency of attack, cough, nasal symptoms, pain in ribs, night symptoms, and immediate relief after expectoration. However, the percentage change was more in Group A. Whereas in symptoms such as duration of attack, wheezing, tachypnea and night symptoms, more percentage change was found in Group B. Statistically insignificant difference was found on cardinal symptoms and vital parameters in between the groups.

Effect of both trail drugs shows highly significant result in comfort in sitting and desire on warmness. Significant result was observed in sweating on forehead and dryness in oral cavity (Group A), whereas in Group B, insignificant result was observed in dryness of oral cavity.

The usage of trial drugs, the duration, frequency, and dosage of the emergency allopathic medicines including steroids

Table 3: Effect of test drugs Group A on chief complaints in comparison to Group B

Chief complaints	Groups	>50%	<50%	Row total	χ^2	*P*
Breathlessness	Group A	21	6	27	0.0648	>0.05
	Group B	26	5	31		
	Total	47	11	58		
Frequency of attack	Group A	15	5	20	0.9428	>0.05
	Group B	26	3	29		
	Total	41	8	49		
Intensity	Group A	13	3	16	6.065	<0.02
	Group B	12	6	18		
	Total	25	9	34		
Duration of attack	Group A	5	4	9	0.0062	>0.05
	Group B	4	6	10		
	Total	9	10	19		
Paroxysm	Group A	23	4	27	0.0116	>0.05
	Group B	25	6	31		
	Total	48	10	58		
Tachypnea	Group A	4	2	6	0.0124	>0.05
	Group B	9	4	13		
	Total	13	6	19		
Wheezing	Group A	23	4	27	0.3234	>0.05
	Group B	28	2	30		
	Total	51	6	57		
Cough	Group A	23	3	26	0.0269	>0.05
	Group B	25	5	30		
	Total	48	8	56		
Chest tightness	Group A	6	3	9	0.8507	>0.05
	Group B	6	0	6		
	Total	12	3	15		
Relief after expectoration	Group A	7	1	8	0.0336	>0.05
	Group B	11	2	13		
	Total	18	3	21		
Nasal symptom	Group A	9	3	12	0.2309	>0.05
	Group B	12	8	20		
	Total	21	11	32		
Night breathlessness	Group A	5	5	10	0.5859	>0.05
	Group B	11	4	15		
	Total	16	9	25		
Night wheezing	Group A	1	3	10	3.153	>0.05
	Group B	9	1	4		
	Total	10	4	14		
Awaking at night	Group A	13	6	19	0.8605	>0.05
	Group B	22	4	10		
	Total	35	10	45		
Throat congestion	Group A	0	1	1	0.4444	>0.05
	Group B	3	0	3		
	Total	3	1	4		

were significantly reduced and in few cases, they were withdrawn. Vital parameters in both groups treated patients shown highly significant reduction in respiratory rate and highly significant increase was found in BHT and PEFR. Effect of therapy on ACT and ACQ shows highly significant results in both treated groups. Most of the patients in their follow-up too did not felt the need of any emergency medication.

Table 4: Effect of *Vasa Avaleha* and Granules of *Vasa Avaleha* drugs on associated symptoms

Symptoms	*n*	Mean±SEM		Change		Actual rank (*D*)	α
		Before time	After time	Mean±SEM	Percentage		
Comfort in sitting							
Group A	22	2.045±0.103	0.090±0.090	1.955±0.103	95.59↑	253	<0.0001
Group B	26	2.269±0.104	0.346±0.146	1.923±0.109	84.75↑	351	<0.0001
Desire of warmness							
Group A	25	1.560±0.183	0.720±0.091	0.840±0.188	53.85↓	91	<0.0001
Group B	30	1.600±0.170	0.866±0.063	0.733±0.165	45.81↓	91	<0.0001
Sweating on forehead							
Group A	11	1.300±0.213	0.300±0.152	1.00±0.210	76.92↓	36	<0.01
Group B	13	1.154±0.104	0.538±0.143	0.615±0.140	53.15↓	36	<0.01
Dryness of oral cavity							
Group A	15	1.200±0.106	0.466±0.133	0.733±0.153	61.08↓	55	<0.01
Group B	17	1.176±0.095	0.882±0.080	0.294±0.113	25.0↓	15	>0.05

↓: Decrease, ↑: Increase, SEM: Standard error of mean

Table 5: Effect of *Vasa Avaleha* and granules of *Vasa Avaleha* on objective criteria

Parameters	*n*	Mean±SEM		Change		Actual rank (*D*)	α
		Before time	After time	Mean±SEM	Percentage		
Need of any reliever drug (/last week)							
Group A	23	3.217±0.087	0.478±0.265	2.739±0.210	85.14↓	231	<0.0001
Group B	28	3.036±0.158	1.036±0.264	2.00±0.241	65.88↓	231	<0.0001
RR/min							
Group A	17	1.963±0.180	1.148±0.087	0.814±0.160	41.47↓	120	<0.0001
Group B	21	2.00±0.167	1.129±0.089	0.871±0.152	43.55↓	210	<0.0001
BHT							
Group A	27	4.333±0.250	2.741±0.248	1.593±0.228	36.76↑	231	<0.0001
Group B	31	5.065±0.153	3.452±0.307	1.613±0.239	31.84↑	253	<0.0001
PEFR							
Group A	27	332.96±10.586	285.74±11.328	47.222±6.724	14.18↑	370	<0.0001
Group B	31	322.71±10.915	270.35±10.600	52.355±6.393	16.22↑	465	<0.0001

↓: Decrease, ↑: Increase, SEM: Standard error of mean, RR: Respiratory rate, BHT: Breath holding time, PEFR: Peak expiratory flow rate

Table 6: Effect of *Vasa Avaleha* and granules of *Vasa Avaleha* on asthma control test and asthma control questionnaire

Parameters	*n*	Mean±SEM		Change		Actual rank (*D*)	α
		Before time	After time	Mean±SEM	Percentage		
ACT							
Group A	27	16.185±0.691	13.037±0.478	3.148±0.426	19.45↓	346	<0.0001
Group B	31	16.903±0.783	12.839±0.718	4.065±0.540	24.04↓	435	<0.0001
ACQ							
Group A	27	2.010±0.287	0.520±0.193	1.490±0.282	74.13↓	28	<0.02
Group B	31	1.975±0.260	0.687±0.236	1.288±0.262	65.22↓	28	<0.02

↓: Decrease, SEM: Standard error of mean, ACT: Asthma control test, ACQ: Asthma control questionnaire

Conclusions

The current study revealed that both trial drugs are effective in the treatment of *Tamaka Shwasa* without manifesting any adverse reactions. Use of modern medicines was also curtailed or withdrawn during the treatment with increased quality of life. Hence, safety can be added as a couplet to the conventional anti-asthmatic drugs.

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Conflicts of interest
There are no conflicts of interest.

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हिन्दी सारांश

वासावलेह एवं वासावलेह ग्रॅन्युल्स का तमकश्वास पर प्रभाव

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ब्रॉन्कियल अस्थमा श्वसन तंत्र की जीर्ण शोथजन्य व्याधि है, जो कि बडी मात्रा मे जनमृत्यु का एक अहम कारण है। औद्योगिकीकरण एवं प्रदूषण का अतिरेक ही इस परिस्थिती के निर्माण का प्रमुख कारण है। आयुर्वेद शास्त्र मे वर्णित तमकश्वास से इस व्याधि की तुलना कर सकते है। कृत्रिम, आधुनिक और विलायती दवाएँ इस व्याधि मे तत्काल लाक्षणिक लाभ प्रदान करते है। किन्तु, यह दवाएँ अनिच्छनीय एवं हानिकारक प्रतिक्रिया भी उत्पन्न करती है। इन सभी परिस्थिति एवं समस्याओं को ध्यान मे रखते हुए आधुनिक जन समुदाय को आयुर्वेद जैसी चिकित्सा प्रणालियों से व्याधि में हानि रहित अच्छे लाभ प्राप्ति की काफी अपेक्षा है। आयुर्वेद शास्त्र मे तमक श्वास की चिकित्सा के संदर्भ मे कई योग वर्णित है, अपितु आधुनिक काल मे चिकित्सा क्षेत्र में इनकी कार्यक्षमता भी प्रस्थापित है। प्रस्तुत अध्ययन का हेतु वासावलेह एवं वासावलेह ग्रॅन्युल्स की कार्यक्षमता का तमकश्वास के रोगीओं मे तुलनात्मक अध्ययन करना है। इस अध्ययन मे कुल ६६ रोगीओं को परिचलन किया गया। इन्हे दो वर्गों मे बाँटा गया। रोगीओं मे प्राप्त परिणामों का चिकित्सकिय लाभ, लाक्षणिक लाभ एवं श्वसन प्रणालि की कार्यक्षमता के संदर्भ मे अवमूल्यन किया गया। चिकित्सा के असर का अवमूल्यन व्यक्तिगत एवं लाक्षणिक अवमूल्यांको के आधार पर किया गया है। परिणामों मे व्याधि के सभी प्रधान एवं गौण लक्षणों में नोंदनीय सकारात्मक सुधार पाये गये। ए.ई.सी. मे नोंदनीय ह्रास तथा पी.ई.एफ.आर. एवं बी.एच.टी. में नोंदनीय वृद्धि पायी गयी। विलायती दवाओं का त्याग, अकस्मात संख्या मे ह्रास और जीवन प्रणालि मे गुणवृद्धि जैसे अवलोकन दोनो वर्ग में प्रधान रूप मे प्राप्त हुए। इस अध्ययन से यह फलित होता है कि ब्रोन्कियल अस्थमा जैसे बिन संक्रमण व्याधियों मे आयुर्वेद जैसी परंपरागत चिकित्सा प्रणालि से नोंदनीय लाभ प्राप्त होता है। और यह औषध विलायती दवाओं के स्थान पर या उनके साथ में लेने से लाभ होता है।