INTERNATIONAL
AYURVEDIC
MEDICAL JOURNAL

IAMJ

Research Article ISSN: 2320 5091 Impact Factor: 4.018

A CLINICAL STUDY TO EVALUATE THE COMBINED EFFICACY OF NEBULIZATION WITH BHARANGI ARKA AND ORAL ADMINISTRATION OF ARDRAKA, NAGAVALLI AND VASA SWARASA IN THE MANAGEMENT OF VEGA KALINA TAMAKA SHWASA VIS-À-VIS EXACERBATION OF BRONCHIAL ASTHMA

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ABSTRACT

Tamaka shwasa is one among the five varieties of *Shwasa roga* produced due to vitiation of *kapha* and *vata dosha*, along with the involvement of *rasa dhatu* in *pranavaha srotas*. It is analogous to Bronchial Asthma described in Western system of Medicine. Inhalation therapy is the novel approach in Bronchial Asthma. Considering the need for the research of Ayurvedic formulation which can be used for inhalation therapy, in the present study *bharangi arka* was selected to administer through nebulization, along with the oral administration of *ardraka, nagavalli* and *vasa swarasa* with honey to evaluate their combined efficacy in the management of *Vega Kalina Tamaka Shwasa*. **Intervention:** Nebulization with 5ml of *Bharangi arka*, followed by 15ml oral administration of *swarasa* of *Ardraka, Nagavalli* and *Vasa* (5ml each) with 5gms of *madhu* as *anupana*, every 8th hourly, for 03 consecutive days. **Method**: It was a single group clinical study with pre and post test design. Pre test assessment of subjective parameters was done on 1st day before the 1st dose of the intervention and the post test assessment was done on 3rd day, after the 9th dose of the intervention. While PEFR was recorded before and after the intervention every 8th hourly for 3 consecutive days. The study has shown statistically highly significant reduction in the subjective parameters with the p value 0.000. Also the result of PEFR assessment revealed an increase in the mean in each dose i.e. before and after the intervention with p value 0.000.
Hence, it was inferred that the intervention selected for the present study possess combined effect in the management of *Vega Kalina Tamaka Shwasa* vis-à-vis Exacerbation of Bronchial Asthma.

Keywords: *Tamaka Shwasa*, Bronchial Asthma, *Bharangi Arka* Nebulization, *Swarasa* and PEFR.

INTRODUCTION

Tamaka Shwasa is one among the five varieties of *Shwasa roga* produced due to vitiation of *kapha* and *vata dosha*, along with the involvement of *rasa dhatu* in *pranavaha srotas*. *Shwasa krichrata, kasa, ghurghuraka* and *prana peedana* appears to be its *pradhana lakshana*[1]. It is analogous to Bronchial Asthma described in Western system of Medicine. 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[2]. Nearly 200 million populations across the globe suffer from asthma. In India, 20 million people are estimated to be suffering from it, this is 10% of global burden.

The prevalence is 15% in adults and 5-7% in children in India[3]. WHO has recognized Asthma as a disease of major public health importance and plays a unique role in the co-ordination of international efforts against the disease. Various public health activities such as International Study of Asthma and Allergies in Childhood (ISAAC), Global Initiative for Asthma (GINA) and Allergic Rhinitis and its Impact on Asthma (ARIA) has been taken up by WHO[4].

In the conventional medicine, breakthrough in the treatment of Bronchial Asthma came into the light with the introduction of inhalation therapy i.e. Nebulization / Aerosol mode of drug administration such as salbutamol and corticosteroids Inhalation mode of administration of drugs has proven to be highly beneficial in saving lives in the respiratory disorders and especially in Bronchial Asthma. Lungs have a large surface area and the lung tissue is more permeable than skin, nasal mucosa and GIT. Thus when a drug is administered directly to the lungs through inhalation thereby the absorption will be fast and ample and in turn produces quick relief of the symptoms. However wide range of toxic side effects of modern medicine, confines its use as a permanent remedy[5].According to the demand of time, Ayurveda also requires some modification in the management of ever increasing disease such as Bronchial Asthma effectively. As approaches with the herbal medicines (phyto-chemicals) have regained their popularity for the treatment of respiratory disorders with their efficacy and safety aspect being supported by controlled clinical studies[6].

There is need for the research of Ayurvedic formulations which can be used for inhalation therapy which are effective as modern inhalation drugs, with least adverse effects and that can be applied in day to day practice. In the present study *Bharangi arka* was selected considering the *katu, tikta, kashaya rasa, laghu guna, ushna veerya* which helps to pacify the aggravated *vata* and *kapha dosha*[7]. Also the phyto-chemical and pharmacological profiles of *bharangi* has been reviewed for its anti-inflammatory, anti-allergic anti-asthmatic, and bronchodilator activities[8].

Aqueous extract of *Bharangi* has also been proved for its anti inflammatory and bronchodilatory activities[9]

Among various forms of inhalation therapy, Nebulization is a process which is a process which involves suspension of fine vaporised liquid droplets otherwise known as aerosol, to administer medication directly in to the respiratory system[10].

In order to deliver the active principles of *bharangi arka* directly to the target organ i.e. lungs and with an intention to establish a new route of drug delivery in Ayurveda, nebulization was selected. Along with *Bharangi arka* nebulization, oral administration of *ardraka, nagavalli and vasa swarasa* along with honey was formulated specifically for the study which has *deepana, pacahana, kapha vatahara, chedana, shwasaghna and kasaghna* properties.

OBJECTIVE OF THE STUDY

To evaluate the combined efficacy of nebulization with *bharangi arka* and oral administration of *swarasa* of *ardraka, nagavalli* and *vasa* in reducing the symptoms of *Vega Kalina Tamaka Shwasa* vis-à-vis Exacerbation of Bronchial Asthma.

MATERIALS AND METHODS

Source of data: Subjects were selected from the OPD and IPD of Government Ayurveda Medical College Hospital, Mysuru.

Study design: It was a single group clinical study with pre and post test design. Out of 32 subjects registered, there were 2 dropouts and the study was completed in 30 subjects.

Inclusion Criteria:

1. Subjects with the signs and symptoms of *Vega Kalina Tamaka Shwasa* vis-àvis Exacerbation of Bronchial Asthma were included.
2. Subjects between the age group of 18-60years were included, irrespective of gender, religion and occupation.
3. **Subjects with PEFR with the range of 100 to 350L/min were included.**
4. Subjects with mild and moderate conditions of Bronchial Asthma as per GINA parameters were included.
5. Subjects who were already on the prophylactic management for bronchial asthma were also included.
6. Conscious and well oriented subjects were included.
7. Both fresh and treated cases were included.

Exclusion Criteria:

1. Subjects with PEFR less than 100L/min were excluded.
2. Subjects suffering from COPD, Acute Respiratory Infection and Pleural Effusion were excluded.
3. Other complicated respiratory diseases having any organic lesion such as tumor or any anatomical defect in the airway were excluded.
4. Pregnant and lactating women were excluded.

Diagnostic and Assessment Criteria:

Diagnosis was made on the basis of history and classical signs & symptoms of *tamaka shwasa* like *shwasa kruchrata, ghurghuraka, kasa, shirogourava, parshwashoola, vamathu prayaha, peenasa* and *shushkasyatha*. Symptoms of exacerbation of Bronchial Asthma like wheezing, breathlessness, and cough were also included.

PEFR of the subjects was assessed before administering the intervention and 20 minutes after the administration of intervention, every 8th hourly for 3 consecutive days.

Statistical Methods:

The results were analyzed statistically by using descriptive statistics, Chi Square test, Crammer's V test, paired samples 't' test and RMANOVA using Service product for statistical solution (SPSS) for windows software.

Intervention:

5 ml *Bharangi arka* for nebulization, immediately followed by 15ml of oral administration of *swarasa* of *ardraka, nagavalli* and *vasa* (5ml each) along with 5gms of *madhu* as *anupana*, every 8th hourly

Duration Of Intervention: 03 days

Assessment Parsmeters And Assessment Schedule:

Assessment was done based on the signs and symptoms for bronchial asthma, the grading are detailed below:

Breathlessness: 0 – No breathlessness, 1–Mild – while walking, can lie down; 2-Moderate- while at rest, prefers sitting; 3-Severe - while at rest, sits upright

Wheeze: 0 – Absent; 1-Mild-Moderate-often only at end expiratory; 2-Moderate loud wheeze throughout expiration 3- Severe loud inspiration & expiratory wheezes

Cough: 0 – absent; 1-Morning bouts/after exercise, do not disturb work; 2 – Continuous cough during day and disturbs morning work; 3 – Continuous day, morning and night cough – disturbs activity.

Sputum: 0 – Absent; 1 – Only in morning; 2 – 4-5times/day; 3 – Continuously

Chest tightness: 0 – Absent; 1 – Mild; 2 – Moderate; 3 – Severe

Pulse rate: 0 – <80/min; 1 – 80-100/min; 2 – 100-120/min; 3 – >120/min

Respiratory rate: 0 – 18-23/min; 1 – 24-30/min; 2 – 31-40/min- >40/min

Assessment Schedule:

Assessment of PEFR was done as per the following schedule:

1st assessment – was done as soon as patient got reported to the Hospital (before nebulization).

2nd assessment – was done 20mins after the first dose of intervention.

3rd assessment – was done before administering the next dose of intervention.

4th assessment – was done after 20mins of the second dose of intervention.

Likewise, 5th to 18th data for assessment were collected and recorded.

Hence 18 data were collected and recorded, every 8th hourly for 3 consecutive days.

In the Present Study, total of 32 subjects were registered. The study was conducted in a single group, out of 32 subjects registered, there were 2 dropouts and the study was completed in 30 subjects. The data was collected from the subjects based on the scoring given to each of the symptoms as mentioned in assessment criteria, on the 1st day (Pre-test) and on 3rd day(post test), while PEFR was recorded before and after the intervention every 8th hourly for 3 consecutive days.

1. **Dyspnoea:**

In the present study it was observed that all the 30 subjects (100%) had moderate dyspnoea before intervention. After the intervention dyspnoea was absent in 28(93.3%) and 2(6.7%) presented with mild dyspnoea.The result on Dyspnoea showed statistically highly significant with p value 0.000

2. **Wheeze:**

In the present study it was observed that all the 30 subjects (100%) had moderate wheeze before intervention. After the intervention wheeze was absent in 28(93.3%) and 2(6.7%) presented with mild wheeze. The result on Wheeze showed statistically highly significant with p value 0.000

3. **Cough:** In the present study among 30 subjects, 26(86.7%) had continuous cough and 4(13.3%) had morning bouts of cough before the intervention. After the intervention cough was absent in 26(86.7%) and 4(13.3%) presented with morning bouts of cough.

The result on Cough showed statistically highly significant with p value 0.000

4. **Sputum:** In the present study among 30 subjects, 23(76.7%) presented with expectoration 4-5

times / day and 7(23.3%) presented only with morning bouts of expectoration before the intervention. After the intervention expectoration was absent in 26(86.7%) and 4(13.3%) presented only with morning bouts of expectoration. The result on Sputum showed statistically highly significant with p value 0.000.

Assessment of other signs and symptoms of the subjects was done before starting the intervention i.e. the pre test assessment on 1st day before the 1st dose of the intervention and the post test assessment was done on 3rd day after the 9th dose of the intervention.

OBSERVATIONS AND RESULT:

5. **Chest Tightness:** In the present study it was observed that all the 30 subjects (100%) had moderate chest tightness before the intervention. After the intervention chest tightness was absent in 28(93.3%) and 2(6.7%) presented with mild chest tightness.The result on Chest Tightness showed statistically highly significant with p value 0.000.

6. **Pulse Rate:** In the present study it was observed that among 30 subjects, 27(90.0%) had pulse rate between 80-100/ min and 3(10%) pulse rate between 100-120/min before intervention.

After the intervention 28(93.3%) had pulse <80/ min and 2(6.7%) with pulse rate between 80-100/min after the intervention.

The result on Pulse rate showed statistically highly significant with p value 0.000.

7. **Respiratory Rate:** In the present study it was observed that among 30 subjects, 22(73.3%) had respiratory rate between 31-40/min and 8(10%) respiratory rate between 24-30/min before intervention. After the intervention 28(93.3%) had respiratory rate between 18 – 23/min and 2(6.7%) between 24-30/min after the intervention. The result on Respiratory rate showed statistically highly significant with p value 0.000.

8. **PEFR:** The clinical trial elicited that there was an increase in PEFR with every dose of intervention and also when compared with PEFR before the 1st dose and after the 9th dose of intervention. On comparing the overall effect of the clinical trial conducted on 30 subjects, which was assessed with respect to the improvement of PEFR, with the 1st dose BI and 9th dose AI.

It was observed that the mean of PEFR, during 1st dose of BI was 122.6667 with SD 15.07071 and it was

increased to 278.3333 with SD 40.52103 in the dose of 9th AI. This showed statistically highly significant increase in PEFR, with p value 0.000

Table no 1: Showing Effect on PEFR Before Intervention of each dose

Parameter	Mean	Std. Deviation	N
PEFR 1st dose BI	122.6667	15.07071	30
PEFR 2nd dose BI	129.3333	18.74205	30
PEFR 3rd dose BI	138.6667	19.78040	30
PEFR 4th dose BI	151.0000	21.55186	30
PEFR 5th dose BI	161.3333	21.92988	30
PEFR 6th dose BI	173.3333	25.50637	30
PEFR 7th dose BI	186.3333	27.47831	30
PEFR 8th dose BI	200.6667	28.63966	30
PEFR 9th dose BI	208.7333	46.90264	30
TOTAL PEFR	p value 0.000		

Illustration No 1: Showing Effect on PEFR Before Intervention of each dose

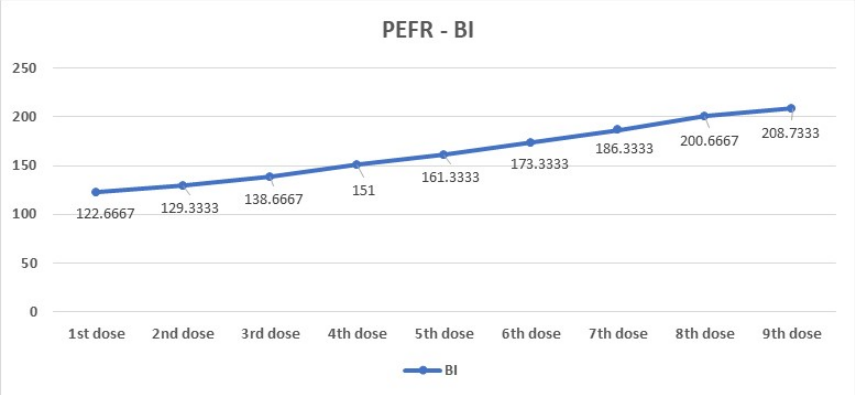


Table no 2: Showing Effect on PEFR 20mins After Intervention of each dose

Parameter	Mean	Std. Deviation	N
PEFR 20mins After 1st dose	162.3333	21.60513	30
PEFR 20mins After 2nd dose	175.3333	24.17370	30
PEFR 20mins After 3rd dose	186.3333	27.09922	30
PEFR 20mins After 4th dose	200.6667	30.61815	30
PEFR 20mins After 5th dose	214.3333	31.47887	30
PEFR 20mins After 6th dose	229.6667	32.00036	30
PEFR 20mins After 7th dose	243.3333	33.66502	30
PEFR 20mins After 8th dose	258.3333	35.53370	30
PEFR 20mins After 9th dose	278.3333	40.52103	30
TOTAL PEFR	p value 0.000		

Illustration No 2: Showing Effect on PEFR After Intervention of each dose

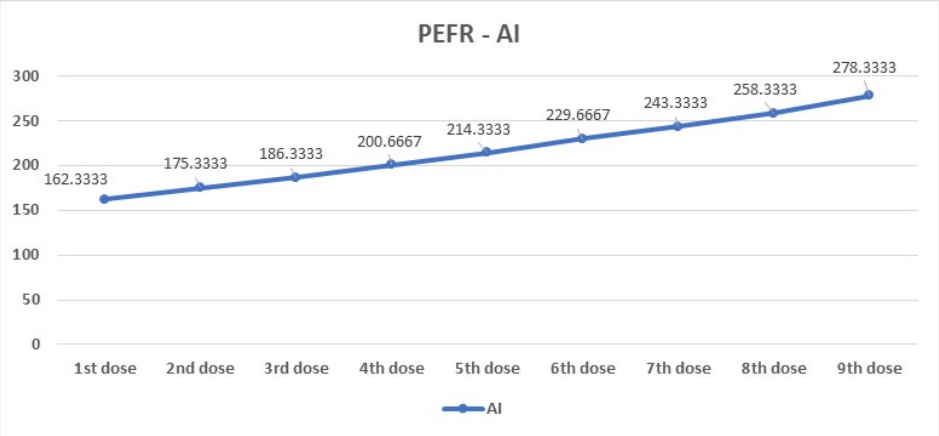
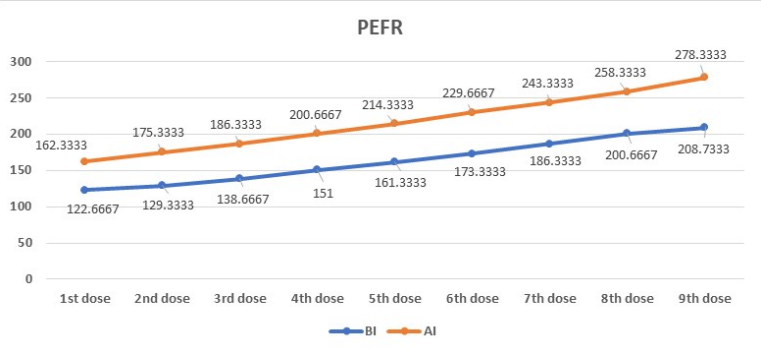


Table no 3: Showing Effect on PEFR before Intervention Vs After Intervention

Parameter	Time	Mean	Std. Deviation	N
D1_PEFR	Before Intervention	122.6667	15.07071	30
	20mins After Intervention	162.3333	21.60513	30
	Total	142.5000	27.22318	60
D2_PEFR	Before Intervention	129.3333	18.74205	30
	20mins After Intervention	175.3333	24.17370	30
	Total	152.3333	31.58881	60
D3_PEFR	Before Intervention	138.6667	19.78040	30
	20mins After Intervention	186.3333	27.09922	30
	Total	162.5000	33.62934	60
D4_PEFR	Before Intervention	151.0000	21.55186	30
	20mins After Intervention	200.6667	30.61815	30
	Total	175.8333	36.28006	60
D5_PEFR	Before Intervention	161.3333	21.92988	30
	20mins After Intervention	214.3333	31.47887	30
	Total	187.8333	37.91568	60
D6_PEFR	Before Intervention	173.3333	25.50637	30
	20mins After Intervention	229.6667	32.00036	30
	Total	201.5000	40.37221	60
D7_PEFR	Before Intervention	186.3333	27.47831	30
	20mins After Intervention	243.3333	33.66502	30
	Total	214.8333	41.88328	60
D8_PEFR	Before Intervention	200.6667	28.63966	30
	20mins After Intervention	258.3333	35.53370	30
	Total	229.5000	43.23468	60
D9_PEFR	Before Intervention	208.7333	46.90264	30
	20mins After Intervention	278.3333	40.52103	30
	Total	243.5333	55.85619	60
TOTAL PEFR		p value 0.000		

Illustration No 3: Showing Effect on PEFR Before Intervention Vs After Intervention



DISCUSSION

Tamaka Shwasa is due to vitiation of *kapha* and *vata dosha*, along with the involvement of *rasa dhatu* in *pranavaha srotas* and characterised by *shwasa krichrata, kasa, ghurghuraka* and *prana peedana*.

Tamaka shwasa in terms of Bronchial Asthma also resembles the same *doshas* and *samprapti*. Hence a combination was chosen based on the following considerations; *Bharangi arka* was selected considering the *katu, tikta, kashaya rasa, laghu guna and ushna veerya* which helps to pacify the aggravated *vata* and *kapha dosha*. Also its phyto-chemical and pharmacological profiles has been reviewed for its anti-inflammatory, anti-allergic anti-asthmatic and bronchodilator activities. In order to deliver the active principles of *bharangi arka* directly to the target organ i.e. lungs and with an intention to establish a new route of drug delivery in Ayurveda, nebulization which is a form of inhalation therapy was selected.

Ardraka Swarasa is a predominant ingredient in many formulations used in the palliation of *Shwasa* by virtue of its *vata kaphahara, ushna veerya* and *kapha nisaraka* properties, which benefits to relieve both *vata kapha* and to relive *margavrodha* in *pranavaha srotas*. It has *deepana* and *pachana* properties, which helps in the prevention of *agni mandya*. *Nagavalli Swarasa*: Leaves of *nagavalli* possess *katu rasa, ushna veerya* and *kapha vatahara* properties and it is indicated in *pranavaha srothovikara*. *Vasa Swarasa*: indicated in the management of *raktapitta, kasa, shwasa* and *rajayakshma.* The *vasa* leaves contain alkaloids such as vasicine and vasicinone, which are proved for its bronchodilation, anti tussive and expectorant properties.

Honey: Honey was selected as *anupana* for administering the *ardraka, nagavalli* and *vasa swarasa*, considering the *yogavahi* property, i.e. it aids easy absorption by active transportation of the constituents of the *swarasa* to the lungs and anti inflammatory and mucolytic properties.

In the present study the results of subjective parameters which were assessed such as dyspnoea, chest tightness, cough, sputum, wheeze, pulse rate and respiratory rate showed statistically highly significant reduction with the p value 0.000. This can be attributed chiefly to the *kapha vata hara, ushna veerya, katu vipaka, bhedana,* anti inflammatory and bronchodilation properties of the drugs present in the intervention. They bring about *kapha vilayana* in the *pranavaha srotas* and thereby relieve the obstruction produced to the passage of *prana vayu* and established the normal *gati* of *vayu*. Therefore the pathological disintegration i.e. broncho constriction gets relieved, in turn dyspnoea, wheeze, chest tightness, cough, increased respiratory rate and pulse rate gets subsided. Similarly the tenacious sputum gets liquefied due to the *ushna veerya, bhedana* and anti tussive properties of the drugs. It also reduces excessive mucus secretion in the srotas. Also the result of the objective parameter i.e. PEFR assessment revealed an increase in the mean in each dose i.e. before and after the intervention. The increase in the mean suggests significant reduction in

the airway obstruction. It also indicates that after each dose of intervention the severity of the condition is getting relieved, which can be attributed to the *kapha vata hara, ushna veerya, katuvipaka, bhedana* and bronchodilation properties of the drugs present in the intervention. Hence, it was inferred that the intervention selected for the present study has shown combined effect in the management of *Vega Kalina Tamaka Shwasa* vis-à-vis Exacerbation of Bronchial Asthma.

Conclusion

Inhalation mode of drug administration proves to be highly beneficial in the treatment of *tamaka shwasa* vis-a-vis bronchial asthma.

An attempt was made in the present study to establish a new route of drug administration in Ayurveda, i.e. nebulization was selected to administer which helps in delivering the active principles of the drug directly to the target organ. *Bharangi arka* was specifically selected to administer through nebulisation considering its *guna, karma,* indications, phyto chemical constituents and properties which are beneficial in subsiding the *vega avasta of tamka shwasa*. Along with nebulization, oral administration of *ardraka, nagavalli* and *vasa swarasa* with honey renders dual action i.e. both the *udbhavasthana* as well as the *adhishtana* of *tamaka shwasa*.

The study was conducted in a single group, consisting of 30 subjects. The results of subjective parameters which were assessed such as dyspnoea, chest tightness, cough, sputum, wheeze, pulse rate and respiratory rate, showed statistically highly significant reduction with the p value 0.000. Also the result of the objective parameter i.e. PEFR assessment revealed an increase in the mean in each dose i.e. before and after the intervention. The PEFR assessed before starting the intervention and after the completion of the intervention also statistically significant improvement with PEFR 0.000 By this it was inferred that *Bharangi arka* Nebulization and oral administration of *Ardraka, Nagavalli* and *Vasa swarasa* showed combined effect in the management of *Vega Kalina Tamaka Shwasa* vis-a-vis Exacerbation of Bronchial asthma,

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Source of Support: Nil
Conflict Of Interest: None Declared

How to cite this URL: Thejaswini R. Et Al: A Clinical Study To Evaluate The Combined Efficacy Of Nebulization With Bharangi Arka And Oral Administration Of Ardraka, Nagavalli And Vasa Swarasa In The Management Of Vega Kalina Tamaka Shwasa Vis-À-Vis Exacerbation Of Bronchial Asthma. International Ayurvedic Medical Journal {online} 2019 {cited March, 2019} Available from: http://www.iamj.in/posts/images/upload/365_372.pdf