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**Shirishavaleha - Promising remedy in bronchial asthma**Shyamlal Singh Yadav<sup>1\*</sup>, Galib<sup>2</sup> and P.K. Prajapati<sup>3</sup>

Department of Rasashastra and Bhaishajya Kalpana including Drug Research,  
Institute for Post Graduate Teaching & Research in Ayurveda, Gujarat Ayurved University, Jamnagar,  
(Gujarat) - India

**Abstract**

WHO surveys of recent past reports approximately 1,80,000 annual deaths because of bronchial asthma, which is a chronic inflammatory disorder of the airways. Increased industrialization and pollution are the exacerbating factors for this situation. In *Ayurveda*, this miserable condition is comparable with a type of *Shwasa Roga*. In the present study, 63 patients were administered with *Shirishavaleha* (Herbal *Ayurvedic* Confection) at a dose of 10 g twice daily for 4 weeks with lukewarm water. The results were assessed in terms of clinical recovery, symptomatic relief and pulmonary function improvement. The effect of the treatment was assessed based on subjective and objective parameters. A significant increase in PEFR, Hb and considerable decrease in absolute eosinophil count (AEC) and E.S.R. were observed. From the study conducted, it was found that 21.15% (10) cases has shown marked improvement, 50.00 % (26) cases shown moderate improvement, 19.23 % (10) cases shown mild improvement and 11.54% (06) of patients remained unchanged. 11 cases were dropped out from the trial. The study reveals that current herbal formulation can be used as an effective drug in bronchial asthma.

**Key-Words:** Avaleha, Bronchial Asthma, Shirisha, Sara, Twak..

**Introduction**

Asthma is one of the most common chronic diseases, with an estimated 300 million individuals affected worldwide. Its prevalence has increased considerably over the past 20 years; especially among children.<sup>1</sup> High rate of prevalence is because of changes in life style, rapid industrialization and increase in air pollution etc. The disease is a common chronic disease affecting all age groups, races and socioeconomic classes globally and its prevalence is changing upwards worldwide.<sup>2</sup> Surveys in adults show high prevalence of asthma symptoms and reduced lung functions particularly in lower socio-economic groups of the sufferers.<sup>3,4</sup> Asthma causes recurring episodes of wheezing, breathlessness, chest tightness and coughing, particularly at night or in the early morning. Common risk factors for asthma include exposure to allergens (such as those for house dust mites, animal with fur, cockroaches, pollens, and mold)<sup>5</sup>, occupational irritants<sup>6</sup>, tobacco smoke<sup>7</sup>, respiratory (viral) infections<sup>8</sup>, chemical irritants<sup>9</sup>, Food allergies such as milk, peanuts and eggs<sup>10</sup> and Psychological stress<sup>11</sup>.

When airways are exposed to any of these risk factors; broncho-constriction will gets manifested leading to inflammation. The airflow becomes limited and the patient suffers with the symptoms of Asthma. The disease is comparable with a type of *Shwasa Roga* in *Ayurveda*<sup>12</sup>. Synthetic drugs definitely provide instant symptomatic relief in these cases, but not complete relief. In addition, they tend to develop a number of adverse drug reactions. Knowing this, the current suffering population is looking hopefully towards few remedies from other systems of medicines, like *Ayurveda*, which are known to provide better relief without manifesting any inconveniencies. Considering all these in view; the current study has been conducted to establish the efficacy of *Shirishavaleha* in cases of Bronchial Asthma. *Shirisha* [*Albizia lebeck* benth], the main composition of the present formulation has multi-dimensional activities, which have been revalidated in different studies of recent past, where the anti allergic<sup>13</sup>, mast cell stabilizing<sup>14</sup> and immunomodulatory activities<sup>15</sup> etc. of the plant have been established. In addition, few clinical trials were also carried-out on different dosage forms of *Shirisha* like *Kwatha* (decoction)<sup>16</sup>, *Asava* (self generated alcoholic preparation)<sup>17</sup> etc. which proved the clinical efficacy in

**\* Corresponding Author:**

E-mail: drshyamlal80@gmail.com

Mob. : +91-9913376548

cases of bronchial asthma. Though, *Kwatha* and *Asava* forms are beneficial, they have their respective limitations in therapeutics.

- The shelf life of *Kwatha* is very less and it is not palatable. Patient feels difficult to swallow it and the doses are to be prepared freshly.
- The pharmaceutical procedure of *Asava* takes long time and it is not easily accepted by few groups of communities, as it contains some percentage of self generated alcohol.

Considering these, *Avaleha* (Confection) form of the composition *Shirisharista* is prepared and its efficacy has been evaluated in cases of Bronchial Asthma.

The useful part advocated for *Shirisha* in classics is *Sara* (heartwood)<sup>18</sup>. One has to destruct the whole plant to collect required amount of *Sara*. If *Twak* (bark) provides similar percentage of relief, one can use bark, instead of heartwood, which saves the plant - *Shirisha*. To check this clinical efficacy, two samples of *Shirishavaleha* are prepared by using *Twak* (bark) and *Sara* (heartwood) of *Shirisha*.

### Material and methods

The study was conducted at OPD and IPD of Institute for Post Graduate Teaching and Research in Ayurveda. Gujarat Ayurved University, Jamnagar. Approval from the institutional ethics committee was obtained prior to initiating the study. By following inclusion and exclusion criterion, 63 patients of both the sex were selected, who have been informed about the details of the trial in brief and prior consent for the trial was obtained from them. 52 patients completed the treatment, whereas 11 patients were dropped out from the study.

The trial drug, *Shirishavaleha* was prepared in the departmental laboratory by following Standard Operative Procedures (SOP). The formulation composition is placed at Table - 01. *Shirishavaleha* prepared with *Twak* was labeled as ST and prepared with *Sara* as SS.

### Criteria for Inclusion

- Both the sexes having age between 20 years to 60 years
- Mild persistent cases of Asthma (as per WHO GINA Guideline) of duration more than 6 months.
- Symptoms/exacerbation (Wheeze, cough and breathlessness) more than once a week
- Difficult expectoration
- Relief after expectoration
- Night symptoms twice a month but less than once a week.

- Relief in erect position

### Criteria for Exclusion

- Age below 20 and above 60 yrs
- Acute asthma requiring emergency measures
- History of Bronchiectasis, Tuberculosis, Pyothorax, Anaemia, Malignancy, Diabetes Mellitus, Hepatic or Renal disease in recent past.
- Dyspnoea resulting from cardiac disease
- HIV positive cases.
- Pregnant/lactating mother.
- *Maha Shwasa*, *Urdha Shwasa* and *Chhinna Shwasa* (types of breathlessness explained in classics) which have been labeled as incurable in *Ayurveda*.

**Investigations:** All the investigations were done before and after treatment of four weeks.

- Routine hematological, including TLC, DLC, Hb, ESR, AEC and Peak Expiratory Flow Rate (PEFR) were done before and after treatment.
- Biochemical investigations like, SGOT, SGPT, Alkaline Phosphatase were carried out to exclude any underlying pathology.
- Sputum examination and chest X-Ray was carried out to exclude pulmonary tuberculosis and other pulmonary diseases.

**Diet and Restrictions:** Patients were advised not to expose to the susceptible triggering or aggravating factors.

**Grouping of Patients & Drug Regimen:** Selected patients were randomly grouped in to two viz. Brief details are as below:

### Assessment Criterion:

The registered patients were advised to visit the OPD at regular intervals of one week. Cases were observed for clinical response. Subjective and objective parameters were recorded in light of improvement in pulmonary functions and other investigations. The assessment of the treatment was made on the basis of the results of the investigations as well as the symptomatic relief. Assessment criterion of the few symptoms is as follows:

#### 1. Frequency of breathlessness

- 0-No attack in the last one month.
- 1-Attack once in a month.
- 2-Attack once in two weeks.
- 3-Attack once in a week.
- 4-Attack twice in a week.
- 5-Attack once or more in a day.

## 2. Intensity of attack

0-Able to do routine work & no treatment intervention is required.

1-Unable to do routine work involving little movements & relief on rest.

2-Unable to talk properly and relief after a dose of drug.

3-Unable to speak and required emergency treatment.

## 3. Duration of attack

0-No episode of attacks.

1-Attack lasting for 10 min

2-Attack lasting for 20 min

3-Attack lasting for 30 min

4-Attack lasting for 40 min and require emergency treatment.

## 4. Use of Emergency Drugs

0-No

1-Occasional

2-Very often

3-Always

**Percentage relief:** in the relief was calculated and assessed based on the below criterion.

< 25%	Poor Response / Unchanged
26% - 50%	Mild Improvement
51% - 75%	Moderate Improvement
76% - 99%	Marked Improvement
100%	Complete Remission

## Results and Discussion

Overall results have been tabulated at Table 2. Four patients (15.38%) of group A and Six patients of (23.06%) group B showed marked improvement. While, ten (38.46 %) patients of group A and sixteen (61.54 %) patients of group B showed moderate improvement. Five (19.13%) patients in group A and one (03.85%) patient group B didn't responded to the treatment. Remaining patients showed mild improvement to their respective treatments.

The reduction in eosinophil count, ESR, TLC and AEC is found to be insignificant, but statistically significant and highly significant results were found in Hemoglobin and PEFr respectively in both the groups. (Table 3 & 4) While statistically significant reduction was found in eosinophils count, ESR and AEC (Table 4)

It was found in the study that, the duration, frequency and dosage of allopathic emergency medicines were drastically reduced and in few cases. Interestingly, most of the patients in their follow-up period too didn't felt the need of any emergency medication, particularly in Group- B. (Table 5)

Ayurveda emphasizes on *Srotorodha* (obstruction of channels) in the manifestation of *Shwasa Roga*. *Srotorodha* is the resultant of disturbance in the equilibrium of *Vata* and *Kapha* (both are humors responsible for physiological functions). Hence drugs, which are beneficial in removing the obstruction and maintain the physiological equilibrium of *Vata* and *Kapha* are useful in this condition.

*Shirisha* is emphasized to be the best *Vishaghna* (anti-allergic) and specifically recommended in *Kasa* and *Shwasa* (diseases of respiratory tract) in *Ayurveda*.<sup>19</sup> The pharmacokinetic properties of the drug - *Shirisha* as per *Ayurveda* (*Madhura, Tikta, Kashaya Rasa, Anushana Veerya, Katu Vipaka*) will be beneficial in counteracting the exacerbated *Kapha* and *Vata doshas*. Its *Vishaghna* property helps in neutralizing the antigens and breaking the pathology at multiple levels. The three saponins of *Shirisha*, known as albiziasaponins (A, B & C) are responsible for the anti-allergic activity of the drug.<sup>28</sup> Studies of recent past revealed anti-allergic,<sup>13</sup> anti-inflammatory,<sup>20</sup> anti-histaminic<sup>21</sup> expectorant action<sup>22</sup> and immuno-modulatory activity<sup>15</sup> of *Shirisha*.

Reduction in the eosinophil count during the treatment elucidated the anti-allergic activity of the formulation. Other components of the formulation like *Pippali* and *Haridra* also have immuno-modulatory<sup>23,24</sup> and anti-histaminic activities. Besides, *Pippali* enhances bioavailability<sup>25</sup>, which helps in maintaining the major therapeutic principles in the systemic circulation for longer duration. Other components reported to have multi-dimensional activities like anti-bacterial<sup>26,27</sup>, anti-histaminic, broncho-dilating, anti-tubercular properties etc. Probably because of these activities, the combination showed the anti asthmatic activity.

The dose, duration and frequency of allopathic emergency medicines were drastically reduced and in few cases withdrawn. Interestingly, most of the patients during follow-up also didn't felt the need of any emergency medication. This response was more in Group B. No adverse effects / reactions have been observed during the course of the treatment.

The results reveal that the compound formulation has a significant action on the pathology of Bronchial asthma and it could suppress total leukocyte count, eosinophil count, ESR and can improve PEFr along with providing symptomatic relief.

Analysis of the data generated during the study shows that *Shirishavaleha* prepared from both bark and heartwood exhibited good activity in *Tamaka shwasa*. However, comparative evaluation shows that drug prepared with heartwood has slightly higher magnitude which is statistically insignificant. Taking overall

results in to consideration, it can be suggested that both bark and heartwood could be used for therapeutic management. Since collection of bark does not involve destructive collection practices; it should be preferred generally. If heartwood is available plentifully, then it can be given preference. Even mixing both of them would also be useful. However, a detailed observational study is required to demonstrate the actual kinetics of the drug at molecular levels.

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	Group	No of patients	Drug	Dose / Day	Adjuant	Duration
1	Group - A	26	ST	10g Twice	Luke warm water	28 days
2	Group - B	26	SS	10g Twice	Luke warm water	28 days

Table 1: Formulation composition of Shirishavaleha

	Ingredient	Botanical Name	Part used	Proportion
1	Shirisha	<i>Albizia lebeck</i> Benth.	Bk. / Ht. Wd.	50 Parts
2	Pippali	<i>Piper longum</i> Linn.	Fr.	1 Part
3	Priyangu	<i>Callicarpa macrophylla</i> Vahl.	Fl.	1 Part
4	Kushta	<i>Saussurea lappa</i> C. B. Clarke	Rt.	1 Part
5	Ela	<i>Elettaria cardemomum</i> Maton.	Sd.	1 Part
6	Nilini	<i>Indigofera tinctoria</i> Linn.	Rt.	1 Part
7	Haridra	<i>Curcuma longa</i> Linn.	Rz.	1 Part
8	Daruharidra	<i>Berberis aristata</i> DC.	St.	1 Part
9	Shunthi	<i>Zingiber officinale</i> Roscoe.	Rz.	1 Part
10	Nagakesara	<i>Mesua ferrea</i> Linn.	Stmn.	1 Part
11	Guda	Jaggery	-	200 Parts
12	Jala (w/w)	Potable water	-	500 Parts

Table 2: Overall effect of the therapy

Relief	Group - A		Group - B		Total	%
	N	%	N	%		
Unchanged	05	19.23	01	03.85	06	11.54
Mild improvement	07	26.92	03	11.54	10	19.23
Moderate improvement	10	38.46	16	61.54	26	50.00
Marked improvement	04	15.38	06	23.06	10	21.15

Table 3: Hematological results of Group A

Parameter	n	Before Treatment	After Treatment	t value	p value
TLC	26	18296.15±424.49	8023.07± 25.21	0.75	>0.05
Eosinophil count	26	3.885± 0.25	3.500± 0.19	1.30	>0.05
ESR	26	14.308± 2.54	13.692± 2.48	0.48	>0.05
AEC	26	321.154±27.05	276.923±17.59	1.54	>0.05
Hb	26	13.219± 0.37	13.412± 0.38	2.09	<0.05*
PEFR	26	240.308±18.508	270.769±19.23	5.22	<0.001**

\*\* Statistically highly significant, \* Statistically significant

Table 4: Hematological results of Group B

Parameter	n	Before Treatment	After Treatment	t value	p value
TLC	26	8257.692±316.43	7903.846±259.673	0.95	>0.05
Eosinophil Count	26	4.385± 0.396	3.269± 0.0887	2.61	<0.02*
ESR	26	17.038± 3.029	14.385± 2.226	2.26	<0.05*
AEC	26	359.615±34.864	253.846±12.065	2.71	<0.02*
Hb	26	12.508± 0.306	12.923± 0.289	2.59	<0.02*
PEFR	26	199.615±13.851	263.462±12.973	6.87	<0.001**

\*\* Statistically highly significant, \* Statistically significant

Table 5: Withdrawal of Emergency Medicine

Group	n	Mean ± SEM		Change		t value	p value
		BT	AT	Mean ± SEM	%		
Group-A	15	1.286±0.184	0.857±0.143	0.429±0.202	33.36↓	2.121	>0.05
Group-B	20	2.100±0.233	0.800±0.249	1.300±0.260	61.90↓	4.993	<0.001**

\*\* Statistically highly significant