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Clinical efficacy of two different samples of *Shirishavaleha* in *Tamaka Shwasa* (Bronchial Asthma)

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Abstract

Incidences of Bronchial Asthma have been raised in recent decades due to increased industrialization and pollution. This miserable condition can be compared with *Tamaka Shwasa* in Ayurveda. Modern synthetic drugs will provide instant relief in these cases, but are tend to develop a number of adverse drug reactions. Knowing this, the current suffering population is looking towards few remedies from other systems of medicines, that are comparatively safe and provide better relief. *Shirisha* [*Albizzia lebbeck* Benth] is a drug with multi-dimensional activities emphasized in Ayurveda for different disease conditions. Considering this, two types of *Shirishavaleha* (confection of *Shirisha*) were prepared by *Kwatha* (decoction) of *Twak* (bark) and *Sara* (heartwood) of *Shirisha* to evaluate its comparative efficacy in *Tamaka Shwasa* (bronchial asthma). The results were assessed in terms of clinical recovery, symptomatic relief and pulmonary function improvement. A significant increase in Hb and considerable decrease in total eosinophil count, AEC and ESR were observed. The study revealed that *Shirishavaleha* can be used as an effective drug in bronchial asthma.

Key words: *Avaleha, Sara, Shirisha, Tamaka Shwasa, Twak*

Introduction

As per the survey of WHO, bronchial asthma is leading to approximately 1,80,000 deaths annually. This data reveals that, bronchial asthma is becoming a global health problem in the present scenario. Increased industrialization and pollution contributed a lot in manifesting and exacerbating this disease. This miserable condition can be compared with a type of *Tamaka Shwasa* in Ayurveda and the etiological factors focused by *Acarya Charaka* like *Rajaso Dhuma Vataabhyaam*..... etc. also mimic with that of the etiological factors of bronchial asthma.[1] Modern therapeutic molecules are known to provide instant relief in these cases, but are tend to develop a number of adverse drug reactions. Knowing this, the current suffering population is looking towards few remedies from other systems of medicines, which can provide better relief and are comparatively safe.

Shirisha [*Albizzia lebbeck* Benth] is a drug with multi-dimensional activities emphasized in Ayurveda for different disease conditions. The therapeutic attributes explained for the drug are *Shwasahara*,[2] *Vishahara*,[3] *Kasahara*[4] etc. Considering its effect in different conditions, a number of studies have been carried out in recent past, which revealed anti-allergic,[5] anti-eosinophilic,[6] anti-inflammatory,[7] etc. activities of *Shirisha*, which provided a lead to use the drug in cases of allergic manifestations. In addition, few clinical trials were also carried-out on different dosage forms of *Shirisha* like *Kwatha* (decoction),[8] *Asava* (self generated alcoholic preparation),[9] etc. which proved the clinical efficacy in cases of bronchial asthma. Though, *Kwatha* and *Asava* forms are beneficial, they have their respective limitations in therapeutics like

- The shelf life of *Kwatha* is very less and it is not palatable to all. In addition *Kwatha* is to be prepared freshly.
- The pharmaceutical procedure of *Asava* takes long time. As it contains some percentage of self generated alcohol, it is not easily acceptable by few communities.

The useful part advocated for *Shirisha* in classics is *Sara* (heartwood).[10] 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 the comparative efficacy of *Sara* and *Twak*, two samples of *Shirishavaleha* was prepared by using *Twak* (bark) and *Sara* (heartwood) of *Shirisha*. The formulation is based on the description of *Shirisharista*.[11]

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Materials and Methods

The study was conducted at OPD and IPD of Rasashastra and Bhaishajya Kalpana including Drug Research, IPGT and RA, 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 1.

Criteria for inclusion

Patients between 20-60 yrs with symptoms of difficult breathing, Paroxysmal attacks of Dyspnoea, Difficult expectoration were included in the study. The signs and symptoms of *Tamaka Shwasa* as described in Ayurvedic classics were also considered while selecting the patients.

Criteria for exclusion

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, *Maha Shwasa*, *Urdha Shwasa* and *Chhinna Shwasa* (incurable types of breathlessness) which have been labeled as incurable in Ayurveda were excluded from the study.

Investigations

Investigations were done before and after treatment of four weeks.

Table 1: Formulation composition of *Shirishavaleha*

Ingredient	Botanical name	Part used	Proportion
Shirisha	*Albizzia lebbeck* Benth.	Bark/Heart Wood	50 Parts
Pippali	*Piper longum* Linn.	Fruit	1 Part
Priyangu	*Callicarpa macrophylla* Vahl.	Flower	1 Part
Kushta	*Saussurea lappa* C. B. Clarke	Root	1 Part
Ela	*Elettaria cardemomum* Maton.	Seed	1 Part
Nilini	*Indigofera tinctoria* Linn.	Root	1 Part
Haridra	*Curcuma longa* Linn.	Rhizome	1 Part
Daruharidra	*Berberis aristata* DC.	Stem	1 Part
Shunthi	*Zingiber officinale* Roscoe.	Rhizome	1 Part
Nagakesara	*Mesua ferrea* Linn.	Stamen	1 Part
Guda	Jaggery	-	200 Parts
Jala (w/w)	Potable water	-	500 Parts

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

Diet and restrictions

Patients were advised not to expose to the susceptible aggravating factors.

Grouping of patients and drug regimen

Patients of Group A received *Shirishavaleha* prepared with *Twak*, while patients of Group B received *Shirishavaleha* prepared with *Sara*. The dose in both the groups was 10g twice a day with luke warm water for 28 days.

Assessment criteria

Efficacy of the treatment was assessed on the basis of relief found on the cardinal signs and symptoms before and after treatment. Laboratory investigations like total leukocyte count, differential count of neutrophils, leukocytes, eosinophils etc, ESR, Hb%, total RBC and Absolute Eosinophil Count (AEC) conducted before and after treatment were also considered while assessing the clinical efficacy.

Percentage 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

Gradation/scoring pattern of cardinal symptoms

1. *Shwasakashtata* (dyspnoea)
   - 0 - No *Shwasakashtata*
   - 1 - *Shwasakashtata* after heavy work, relieved by rest
   - 2 - *Shwasakashtata* on slight exertion
   - 3 - *Shwasakashtata* even at rest
2. Frequency of *Shwasa Vega* (attacks):
   - 0 - No attack during one month
   - 1 - Frequency of attack once in a month
   - 2 - Frequency of attack once in two weeks
   - 3 - Frequency of attack once in a week
   - 4 - Frequency of attack twice in a week
   - 5 - Frequency of attack once or more than once in a day.
3. Intensity of attack:
   - 0 - Able to do routine work and no treatment intervention is required.
   - 1 - Unable to do work involving little movement and relief on rest.
   - 2 - Unable to talk properly and relief after booster dose of thesis drug.
   - 3 - Unable to speak and required emergency treatment.
4. *Kasa* (cough)
   - 0 - No *Kasa*
   - 1 - *Kasavega* sometimes but does not troublesome.
   - 2 - Troublesome *Kasa*, but does not disturbing the sleep.

3 - Very troublesome *Kasa*, does not even allowing sleeping at night.

5. *Urahshula/Parshvashula* (pain in chest and costal margins)
   0 - No *Urahshula/Parshvashula*
   1 - *Urahshula/Parshvashula* along with the attack
   2 - Very often *Urahshula/Parshvashula* even without attack
   3 - Always *Urahshula/Parshvashula*

Observations and results

Majority of the cardinal symptoms explained in Ayurvedic classics for *Tamaka Shwasa* were observed in the patients [Figure 1].

Cardinal symptoms

Both groups have shown significant result at $P < 0.01$ level over frequency, intensity as well as duration of dyspnoea. But the change was more in Group - B (55.06%, 55.55% and 58.2%) than that of Group - A (40.45%, 50.23% and 53%). Highly significant results were obtained on *Kasa*, *Kapha Sthivana* and *Peenasa* in both groups ($P < 0.001$) while percentage change was more in Group - B. Results on *Parshwa Shoola* were found to be significant in Group - A ($P < 0.05$) while in Group - B it was highly significant ($P < 0.01$) [Table 2].

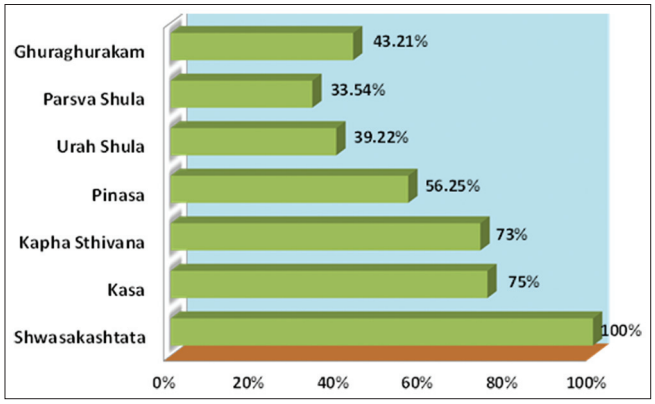

Figure 1: Cardinal symptoms of *Tamaka Shwasa*

Effect on intake of emergency medicine

With the usage of both the trial drugs; the duration, frequency and dosage of the emergency allopathic medicines including steroids etc were drastically reduced and in few cases they were withdrawn. Interestingly, most of the patients in their follow-up did not feel the need of any emergency medication. Also patients reported improvement in quality of life.

On hematocrit values

Hematocrit parameters in Group - A treated patients showed insignificant reduction in lymphocytes, eosinophils, E.S.R., T.L.C and A.E.C., but non-significant increase was found in neutrophil and statistically significant increase was found in percentage of hemoglobin. Hematocrit parameters in Group - B treated patients showed statistically insignificant reduction in T.L.C and insignificant increase in lymphocytes, neutrophil but statistically significant increase in hemoglobin percentage, and statistically significant reduction in eosinophils %, E.S.R. and A.E.C [Tables 3 and 4].

Overall effect of therapy

Maximum 50% of the patients were shown moderate improvement, followed by 21.15% patients with marked

Table 2: Effect of the treatment on cardinal symptoms

Group	*n*	Mean±S.E.M.		Change		*'t'*	*'P'*
		B.T.	A.T.	Mean±S.E.M.	%		
Effect of drugs on frequency of dyspnoea							
Group-A	26	3.231±0.231	1.923±0.241	1.308±0.270	40.45↓	4.835	<0.001
Group-B	24	1.885±0.150	0.846±0.154	1.038±0.152	55.06↓	6.845	<0.001
Effect of drugs on intensity of dyspnoea							
Group-A	26	2.130±0.220	1.060±0.219	1.070±0.112	50.23↓	8.446	<0.001
Group-B	23	1.800±0.200	0.800±0.200	1.000±0.149	55.55↓	6.708	<0.001
Effect of drugs on duration of dyspnoea							
Group-A	26	1,910±0.250	0.900±0.250	1.090±0.160	53%↓	4.231	<0.001
Group-B	24	1.7 00±0.180	0.880±0.242	0.820±0.131	58.2 ↓	4.725	<0.001
Effect of drugs on *kasa*							
Group-A	25	2.154±0.143	0.923±0.175	1.231±0.178	57.15↓	6.911	<0.001
Group-B	24	1.346±0.156	0.500±0.114	0.846±0.120	62.85↓	7.042	<0.001
Effect of drugs on *kapha nishtivana*							
Group-A	15	0.923±0.183	0.423±0.126	0.500±0.114	54.17↓	4.372	<0.001
Group-B	16	0.962±0.196	0.231±0.0843	0.731±0.152	75.98↓	4.792	<0.001
Effect of drugs on *peenasa*							
Group-A	22	1.192±0.136	0.385±0.125	0.808±0.147	67.78↓	5.496	<0.001
Group-B	20	1.231±0.169	0.231±0.0843	1.000±0.147	81.23↓	6.814	<0.001
Effect of drugs on *parshwa shoola*							
Group-A	13	1.700±0.210	0.800±0.300	0.830±0.170	56.20 ↓	1.756	<0.05
Group-B	10	1.20±0.190	0.400±0.24	0.800±0.212	66.60 ↓	3.436	<0.001

Data: Mean±SEM; ↓: Decrease

improvement and 19.23% with mild improvement. 11.54 % of the registered patients did not show much change. Both the drugs have shown significant results but Group - B is found to be marginally better than Group - A; however, it is statistically insignificant [Tables 5, 6 and Figure 2].

Discussion

Ayurveda emphasizes on *Srotorodha* (obstruction of channels) in the manifestation of *Swasa 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*.[12] The pharmacokinetic properties of the drug - *Shirisha* as per *Ayurveda* (*Madhura*, *Tikta*, *Kashaya Rasa*, *Anushana Veerya* and *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 and C) are responsible for the anti-allergic activity of the drug.[13] Studies of recent past revealed anti-allergic,[14] anti-inflammatory,[15] anti-histaminic[16] expectorant action[17] and immuno-modulatory activity[18] of *Shirisha*. Reduction in the eosinophil count

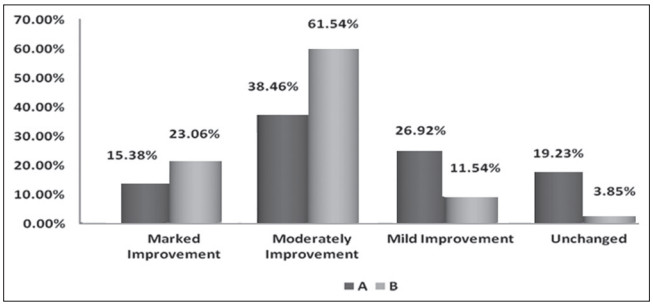

Figure 2: Comparative effect of the drugs

Table 3: Effect of Group - A on haematocrit values (*n*=26)

Parameter	B.T.	A.T.	B.T.-A.T.	Change (%)	't'	'P'
TLC	8296.15±424.49	8023.07±25.21	273.077±343.491	03.292↓	0.795	>0.05
Neutrophil	62.385±1.060	62.538±0.958	–0.154±0.884	00.247↑	0.174	>0.05
Eosinophil	3.885±0.256	3.500±0.194	0.385±0.294	09.910↓	1.309	>0.05
Lymphocyte	32.654±1.845	30.615±0.977	2.038±1.821	06.241↓	1.120	>0.05
E.S.R.	14.308±2.539	13.692±2.487	0.615±1.273	04.301↓	0.483	>0.05
Hb	13.219±0.374	13.412±0.383	-0.192±0.0918	01.452↑	2.095	<0.05
AEC	321.154±27.057	276.923±17.592	44.231±28.599	13.773↓	1.547	>0.05

Data: Mean±SEM; ↑: Increase; ↓: Decrease

Table 4: Effect of Group - B on haematocrit values (*n*=26)

Parameter	B.T.	A.T.	B.T.-A.T.	Change (%)	't'	'P'
TLC	8257.692±316.431	7903.846±259.673	353.846±372.362	04.285↓	0.950	>0.05
Neutrophil	60.808±1.475	61.692±1.357	-0.885±1.362	01.455↑	0.649	>0.05
Eosinophil	4.385±0.396	3.269±0.0887	1.115±0.427	25.427↓	2.611	<0.02
Lymphocyte	31.962±1.392	32.000±1.301	-0.0385±1.422	00.120↑	0.0270	>0.05
E.S.R.	17.038±3.029	14.385±2.226	2.654±1.171	15.577↓	2.266	<0.05
Hb	12.508±0.306	12.923±0.289	-0.415±0.160	03.317↑	2.597	<0.02
AEC	359.615±34.864	253.846±12.065	105.769±38.960	29.387↓	2.715	<0.02

Data: Mean±SEM; ↑: Increase; ↓: Decrease

Table 5: Comparative effect of both the drug in cardinal symptoms

Symptoms	*n*	Group-A	Group-B	't'	%	'P'
Shwasa Vega (Frequency of dyspnoea)	50	1.308±0.270	1.038±0.152	0.871	20.64↓	>0.05
Shwasa Tivrata (Intensity of dyspnoea)	49	1.070±0.112	1.000±0.149	0.375	06.54↓	>0.05
Duration of attack	50	1.090±0.160	0.820±0.131	1.305	24.77↓	>0.05
Kasa (Cough)	49	1.231±0.178	0.846±0.120	1.791	31.27↓	>0.05
Sakaphakasa (Productive cough)	31	0.500±0.114	0.731±0.152	-1.211	-46.20↑	>0.05
Peenasa (Rhinitis)	42	0.808±0.147	1.000±0.147	-0.926	-23.76↑	>0.05
Parshwashoola (Pain in ribs)	23	0.830±0.170	0.800±0.212	0.271	03.61↓	>0.05
Ronchi	44	0.423±0.098	0.769±0.139	-2.027	-81.79↑	<0.05

Data: Mean±SEM; ↑: Increase; ↓: Decrease

Table 6: Overall effect of 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	11	21.15

during the treatment elucidated the anti-allergic activity of the formulation.

Recent studies have also proven Anti-tussive,[19] Immuno-modulatory[20] and Anti-inflammatory[21] activities of *Shirishavaleha*. Other components of the formulation like *Pippali* and *Haridra* also have immuno-modulatory[22,23] and anti-histaminic activities. Besides, *Pippali* enhances bioavailability,[24] 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,[25,26] 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 they have been withdrawn. Interestingly, most of the patients during follow-up period 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. 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.

Conclusion

Both groups showed good results in reduction of symptoms of *Tamaka Shwasa* along with statistical significance of objective parameters like absolute eosinophil count, expiratory peak flow rate, ESR and TLC. Comparative analysis of both groups revealed slightly better response in Group B, which is statistically insignificant. Taking overall results in to consideration, it can be suggested that *Shirishavaleha* prepared either with bark or heartwood can be used in the therapeutic management of *Tamaka Shwasa* (bronchial asthma), which is safe and free from adverse drug reactions.

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हिन्दी सारांश

शिरीष त्वक् एवं सार के क्वाथ से निर्मित शिरीषावलेह का तमकश्वास पर तुलनात्मक चिकित्सकीय अध्ययन

श्यामलालसिंह यादव, गालिब, बिस्वाज्योति पटगिरी, प्रदीपकुमार प्रजापति

वर्तमान युग में बढ़ते औद्योगिकरण एवं प्रदूषण के कारण लोगों में दमा की प्रवृति भी बढ़ी है । इस भयानक स्थिति की तुलना आयुर्वेद में तमक श्वास से कर सकते हैं । आधुनिक चिकित्सा औषध तत्काल लाभ पहुंचाती है लेकिन इसके अनेक हानिकारक प्रभाव भी हैं । इसको देखते हुए वर्तमान पीड़ित जनसमुदाय का ध्यान ऐसी चिकित्सा पद्धति पर आकर्षित हो रहा है जो इनकी तुलना में सुरक्षित तथा अधिक प्रभावकारी है । शिरीष एक ऐसी वनौषधि है जो विभिन्न रोगों में अपने अनेक कर्मों सहित आयुर्वेद में उपदिष्ट है । इसको ध्यान में रखकर शिरीषावलेह का निर्माण शिरीष के त्वक् एवं सार द्वारा निर्मित क्वाथ से, तमक श्वास में तुलनात्मक प्रभाव का मूल्यांकन करने हेतु किया गया । परिणाम का मूल्यांकन चिकित्सकीय आरोग्यलाभ, लाक्षणिक लाभ, फुप्फुस कर्म लाभ के संदर्भ में किया गया है । हिमोग्लोबिन में सार्थक वृद्धि पायी गई और पूर्ण इयोसिनोफिल काउण्ट एवं ई.एस.आर. में महत्वपूर्ण कमी देखी गई । तुलनात्मक अध्ययन से स्पष्ट होता है कि सार क्वाथ से निर्मित शिरीषावलेह त्वक क्वाथ से निर्मित शिरीषावलेह से अधिक प्रभावी है परन्तु यह अन्तर सांख्यकी दृष्टि से सार्थक नहीं है ।