Clinical Research

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 Vataabhyaan…… etc. also mimic with that of the etiological factors of bronchial asthma. 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,[1] Kasahara[8] 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),[3] 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]
Materials and Methods

The study was conducted at OPD and IPD of Rasashastra and Bhaisajya 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, 65 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, Urdhva Shwasa and Chhinta 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 |
| Kushtha    | 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 |

Table 1: Formulation composition of Shirishavaleha

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.

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 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
3. Very troublesome Kasa, does not even allowing sleeping at night.
4. Urahshula/Parshvashula (pain in chest and costal margins)
5. Urahshula/Parshvashula along with the attack
6. Always Urahshula/Parshvashula even without attack

**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].

**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 improvement.

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**Table 2: Effect of the treatment on cardinal symptoms**

| Group   | n  | Mean±S.E.M. B.T. | Mean±S.E.M. A.T. | Change Mean±S.E.M. | 't'  | 'P'   |
|---------|----|-----------------|-----------------|-------------------|-----|-------|
| Effect of drugs on frequency of dyspnoea | Group-A | 26 | 3.23±0.231 | 1.92±0.241 | 1.308±0.270 | 40.45 | 4.835 <0.001 |
|         | Group-B | 24 | 1.88±0.150 | 0.84±0.154 | 1.038±0.152 | 55.06 | 6.845 <0.001 |
|         |         |         |               |               | 4.835 | 6.845 <0.001 |
| Effect of drugs on intensity of dyspnoea | Group-A | 26 | 2.13±0.220 | 1.06±0.219 | 1.070±0.112 | 50.23 | 8.446 <0.001 |
|         | Group-B | 23 | 1.80±0.200 | 0.80±0.200 | 1.000±0.149 | 55.55 | 6.708 <0.001 |
|         |         |         |               |               | 5.025 | 6.708 <0.001 |
| Effect of drugs on duration of dyspnoea | Group-A | 26 | 1.91±0.250 | 0.90±0.250 | 1.090±0.160 | 53% | 4.231 <0.001 |
|         | Group-B | 24 | 1.70±0.180 | 0.88±0.242 | 0.820±0.131 | 52.8 | 4.725 <0.001 |
| Effect of drugs on kasa | Group-A | 25 | 2.15±0.143 | 0.92±0.175 | 1.231±0.178 | 57.15 | 6.911 <0.001 |
|         | Group-B | 24 | 1.34±0.156 | 0.50±0.114 | 0.846±0.120 | 62.85 | 7.042 <0.001 |
| Effect of drugs on kapha nishtivana | Group-A | 15 | 0.92±0.183 | 0.42±0.126 | 0.500±0.114 | 54.17 | 4.372 <0.001 |
|         | Group-B | 16 | 0.96±0.196 | 0.23±0.0843 | 0.731±0.152 | 75.98 | 4.792 <0.001 |
| Effect of drugs on peenasa | Group-A | 22 | 1.19±0.136 | 0.38±0.125 | 0.808±0.147 | 67.78 | 5.496 <0.001 |
|         | Group-B | 20 | 1.23±0.169 | 0.23±0.0843 | 1.000±0.147 | 81.23 | 6.814 <0.001 |
| Effect of drugs on parshwa shoola | Group-A | 13 | 1.70±0.210 | 0.80±0.300 | 0.830±0.170 | 56.20 | 1.756 <0.05 |
|         | Group-B | 10 | 1.20±0.190 | 0.40±0.24 | 0.800±0.212 | 66.60 | 3.436 <0.001 |

Data: Mean±SEM; 't': 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. 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 albiziasesponins (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

**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   | 273.07±343.491  | 0.392↓     | 0.795 >0.05 |
| Neutrophil     | 62.385±1.060    | 62.538±0.958    | -0.154±0.884    | 0.0247↑    | 0.174 >0.05 |
| Eosinophil     | 3.885±0.256     | 3.500±0.194     | 0.385±0.294     | 0.9910↓    | 1.309 >0.05 |
| Lymphocyte     | 32.654±1.845    | 30.615±0.977    | 2.038±1.821     | 0.624↑     | 6.120 <0.05 |
| E.S.R.         | 14.308±2.539    | 13.692±2.487    | 0.615±1.273     | 0.430↑     | 0.483 >0.05 |
| Hb             | 13.219±0.374    | 13.412±0.383    | -0.192±0.918    | 0.145↑     | 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 | 0.425↓     | 0.950 >0.05 |
| Neutrophil     | 60.808±1.475    | 61.692±1.357    | -0.885±1.362    | 0.045↑     | 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   | 0.0120↑    | 0.027 >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    | 0.317↑     | 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 immune-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 antibacterial;[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 leucocyte 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. If bark is used, as observed earlier, it can be used without any adverse drug reactions.

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 into 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 क्राथ से निर्मित शिरीषावलेह का तमकश्वास पर
tुलनात्मक चिकित्सकीय अध्ययन

श्यामनालसिंह यादव, गालिब, विस्वाज्योति पटगिरी, प्रदीपकुमार प्रजापति

वर्तमान सुन में बढ़ते ओषधिगत क्रय एवं प्रदूषण के कारण लोगों में दम की प्रकृति भी बदल गई है। इस भयानक स्थिति की तुलना आयुर्वेद में तमक श्वास से कर सकते हैं। आधुनिक चिकित्सा ओषध कालाकाल लाभ पहुंचाती है लेकिन इसके अनेक व्यक्तिकों 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 वनोधि है जो विभिन्न रोगों में अपने अनेक कर्म सहित आयुर्वेद में उपद्रव है। इसके ध्यान में स्थान देखते हुए शिरीषावलेह का निर्माण शिरीष के त्वक् एवं सार द्वारा निर्मित क्राथ से, तमक श्वास में तुलनात्मक प्रभाव का मूल्यांकन करने हेतु किया गया।

परिणाम का मूल्यांकन चिकित्सकीय आरोप, लाखकृत काल, पुष्पकृत काल के संदर्भ में किया गया है। हिमोग्लोबिन में सार्थक वृद्धि पायी गई और पूर्ण इंयोसिनोफिल काउंट एवं इ.एस.आर. में महत्त्वपूर्ण कमी देखी गई।

तुलनात्मक अध्ययन से स्पष्ट होता है कि सार क्राथ से निर्मित शिरीषावलेह त्वक् णाथ से निर्मित शिरीषावलेह से अधिक प्रभावी है परन्तु यह अन्तर सांख्यिकी दृष्टि से सार्थक नहीं है।