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..
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) [18]. 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.

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 patients (38.46%) of group A and sixteen (61.54%) patients of group B showed moderate improvement. Five patients (19.13%) in group A and one 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 also 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 Shwas 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 Shwas (diseases of respiratory tract) in Ayurveda. 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. Studies of recent past revealed anti-allergic, anti-inflammatory, anti-histaminic and immuno-modulatory activity 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 and anti-histaminic activities. Besides, Pippali enhances bioavailability, 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, anti-histaminic, broncho-dilating, anti-tubercular properties and many others. 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
During the course of study, 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.

Acknowledgment

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References


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19. Chopra RN, Chopra IC, Verma BS; Supplementary to glossary of Indian Medicinal Plants. CSIR, New Delhi, 1969, pp. 4-5.


<table>
<thead>
<tr>
<th>Group</th>
<th>No of patients</th>
<th>Drug</th>
<th>Dose / Day</th>
<th>Adjuant</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Group - A</td>
<td>26</td>
<td>ST</td>
<td>10g Twice</td>
<td>Luke warm water</td>
</tr>
<tr>
<td>2</td>
<td>Group - B</td>
<td>26</td>
<td>SS</td>
<td>10g Twice</td>
<td>Luke warm water</td>
</tr>
</tbody>
</table>

Table 1: Formulation composition of Shirishavaleha

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

Table 2: Overall effect of the therapy

<table>
<thead>
<tr>
<th>Relief</th>
<th>Group - A</th>
<th>Group - B</th>
<th>Total</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>Unchanged</td>
<td>05 19.23</td>
<td>01 03.85</td>
<td>06</td>
<td>11.54</td>
</tr>
<tr>
<td>Mild improvement</td>
<td>07 26.92</td>
<td>03 11.54</td>
<td>10</td>
<td>19.23</td>
</tr>
<tr>
<td>Moderate improvement</td>
<td>10 38.46</td>
<td>16 61.54</td>
<td>26</td>
<td>50.00</td>
</tr>
<tr>
<td>Marked improvement</td>
<td>04 15.38</td>
<td>06 23.06</td>
<td>10</td>
<td>21.15</td>
</tr>
</tbody>
</table>
Table 3: Hematological results of Group A

<table>
<thead>
<tr>
<th>Parameter</th>
<th>n</th>
<th>Before Treatment</th>
<th>After Treatment</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLC</td>
<td>26</td>
<td>18296±424.49</td>
<td>8023.07±25.21</td>
<td>0.75</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Eosinophil count</td>
<td>26</td>
<td>3,885±0.25</td>
<td>3,500±0.19</td>
<td>1.30</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>ESR</td>
<td>26</td>
<td>14.308±2.54</td>
<td>13.692±2.48</td>
<td>0.48</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>AEC</td>
<td>26</td>
<td>321.154±27.05</td>
<td>276.923±17.59</td>
<td>1.54</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Hb</td>
<td>26</td>
<td>13.219±0.37</td>
<td>13.412±0.38</td>
<td>2.09</td>
<td>&lt;0.05*</td>
</tr>
<tr>
<td>PEFR</td>
<td>26</td>
<td>240.308±18.508</td>
<td>270.769±19.23</td>
<td>5.22</td>
<td>&lt;0.001**</td>
</tr>
</tbody>
</table>

** Statistically highly significant, * Statistically significant

Table 4: Hematological results of Group B

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

** Statistically highly significant, * Statistically significant

Table 5: Withdrawal of Emergency Medicine

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Mean ± SEM</th>
<th>Change</th>
<th>t value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>BT</td>
<td>AT</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group-A</td>
<td>15</td>
<td>1.286±0.184</td>
<td>0.429±0.202</td>
<td>33.36↓</td>
<td>2.121</td>
</tr>
<tr>
<td>Group-B</td>
<td>20</td>
<td>2.100±0.233</td>
<td>1.300±0.260</td>
<td>61.90↓</td>
<td>4.993</td>
</tr>
</tbody>
</table>

** Statistically highly significant