A Clinical Comparative Study To Evaluate The Efficacy Of Shirishadi Syrup and An Established Ayurvedic Marketed Preparation In The Management Of Respiratory Allergic Disorders In Children.

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ABSTRACT

In India prevalence of respiratory allergy disease in school going children have been reported between 5-20% in the different geographic region. The increase in prevalence may be attributed to environmental factors, dietetic incompatibilities, and faulty lifestyle. Respiratory Allergic Disorders (R.A.D.) mainly includes- Allergic bronchitis or Allergic asthma & Allergic rhinitis. As RAD can be co-related with Kasa, Tamak Shwasa in Ayurveda. In the preventive aspect of the disease, Ayurveda has a unique concept of Vyadhikshamatava, various measures and recipes are described to achieve it. Considering these facts a randomized control trial was planned for 12 weeks to evaluate the efficacy of hypothetical Ayurvedic compound Shirishadi Syrup and an established Ayurvedic marketed preparation in children those were suffering from Respiratory Allergic Disorder (R.A.D.). For the study affected children of age group, 5 to 10 years were selected from O.P.D. & I.P.D. of Bal-Roga Dept. of N.I.A. Jaipur. The study was conducted on total 60 patients with 30 patients in each group. Group A- Shirishadi Syrup and Group B- an Established Ayurvedic Marketed Preparation. Statistically extremely significant results were seen in most of the symptoms and also in laboratory parameters in both the groups. After statistical evaluation, it was concluded that both the drugs are equally effective in terms of improvement in previous symptoms of RAD. No adverse effect of the study drug was observed during the study.

Keywords: R.A.D., Kasa, Tamak Shwasa, Vyadhikshamatava, Shirishadi Syrup.

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Introduction:

“Allergy is a hypersensitivity disorder of the immune system of the human body[1].” Allergic reactions
occur when a person’s immune system reacts abnormally to normally harmless substances, present in the environment as well as in body. A substance that causes a reaction is called an allergen. Allergy is formally called type 1 (or immediate) hypersensitivity and is one of four or more forms of hypersensitivity.

Approximately 10% to 30% of individuals in the industrialized world are affected by allergic conditions and this number is increasing. Also in India, the burden of allergic disease has been on an uprising trend in terms of prevalence as well as severity. These allergic diseases comprise of asthma, rhinitis, anaphylaxis, drug, food, and insect allergy eczema and urticaria and angioedema. Approximately 20% to 30% of the total population suffers from at least one of these allergic diseases in India[1].

Childhood asthma among children 13 to 14 years of age has been lower than that in younger children (6 to 7 years of age)[2]. In India prevalence of respiratory allergy disease in school going children have been reported between 5-20% in the different geographic region. Male to female ratio percentage is 64:36 in respiratory allergic disease[3]. The prevalence peaks late in childhood[4].

The prevalence of these disorders in developing as well as developed countries are increasing over the recent decade. The increase in prevalence may be attributed to environmental factors (Rajasa, Dhoom), dietetic incompatibilities (Rukshana, Vishamasan) and faulty lifestyle (Ativyayama, Gramyadharma)[5, 6]. There are different allergic reaction seen in the body-Skin (itching, hives & urticaria), Nasal (sneezing, running nose, itchy nose), Eyes (conjunctivitis), GIT (nausea, vomiting, cramping, diarrhea), Respiratory (shortness of breath, wheezing, coughing, Chest tightness), Cardiovascular (hypotension, palpitation) symptoms.

Respiratory Allergic Disorders (R.A.D.) mainly includes Allergic bronchitis or Allergic asthma & Allergic rhinitis. Allergic asthma is a chronic inflammatory condition of lung airway resulting in episodic airflow obstruction. This chronic inflammation heightens the ‘twitchiness’ of the airways (i.e. airway hyper-responsiveness to provocative exposures). According to modern medicines, its management includes Antihistaminic, Bronchodilators, Mast cell stabilizers, and Corticosteroids. This regimen of the drug only suppress the symptoms and also causes adverse effects like tachycardia, tremors, hypokalemia, headache, sedation, weight gain, oral thrush, reflex coughing etc.[4]

There is no description of allergy found in Ayurveda but Acharyas mentioned various etiological factors which cause various diseases like Vatika Pratishyaya, Shirah Shoola, Aagantuja-Kshavathu, Shwasa- Kasa etc. can be included under allergic disorders.

As RAD can be co-related with Kasa, Tamaka Shwasa in Ayurveda and according to Ayurveda these are caused by faulty diets (Viruddha Asatmya, Ahita Aahara) and lifestyles. This results in Agnimandya (Indigestion) which leads to Aam (Toxins) formation and hence the disease.

Ayurveda also has a unique concept of Vyadhikshamatava and various measures and recipes are described to achieve it. Considering these facts a clinical trial is being done to evaluate the effect of a hypothetical Ayurvedic compound shririshadi syrup on Respiratory Allergic Disorder (R.A.D.) in children. The herbal medicines present in this compound have properties of Rasayana, Aampachana, Anti-allergic, Anti-inflammatory, Mucolytic and Immunomodulatory effect.

Aims and objectives of the study-
1. To assess the effect of Shirishadi Syrup with an established Ayurvedic marketed preparation (LOBODIL Suspension) on Respiratory allergic disorders.
2. To provide the relief or improvement in previous symptoms.
3. To restore normal airway function and to promote a healthy lifestyle.
Material and Methods:

- **Study type:** Open controlled trial
- **Sample selection:** Randomized sampling method.
- **IEC Approval:** Clinical study was approved by IEC, order no. F10 (5)/EC/2014/7220 dated 7/11/2014.
- **Age group:** 5 to 10 years
- **Study center:** OPD and IPD of Dept. of Balroga, N.I.A. Jaipur & Local schools

**Pre-assessment (Screening):** Selected children were screened out by the symptom checklist in the form of pre-assessment questionnaire constituting 14 questions.

**Parents of the concerned child were asked to fill up the questionnaire (Source-AAAI, 2004; 93:36-48).**

A child scoring 7 out of the first 10 questions is considered as asthmatic (allergic) and, one out of next three is considered to have the nasal allergy. The next four questions are related to the severity of the previous episodes and treatment taken.

**Administration of drug and grouping:** After screening a total of 67 patients were registered and randomly divided into two groups out of which 07 patients dropped out and they were treated according to the following schedule –

<table>
<thead>
<tr>
<th>Table No. I Drug Posology And Grouping</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group A (N=30)</strong></td>
</tr>
<tr>
<td><strong>Trial Drug (Shirishadi syrup)</strong></td>
</tr>
<tr>
<td>Dose</td>
</tr>
<tr>
<td>Dosage form</td>
</tr>
<tr>
<td>Route</td>
</tr>
<tr>
<td>Anupama</td>
</tr>
<tr>
<td>Duration</td>
</tr>
</tbody>
</table>

- **Follow up:** The clinical follow-ups were taken fortnightly.

**Parents’ Consent / Child Assent:** A voluntary, signed witnessed informed consent/assent was obtained from the participant/parent’s/ Guardians prior to the start of the clinical trial.

**Inclusion criteria:**

- Recurrent Bronchitis, Laryngitis, Sinusitis, Common cold.
- Past H/O Recurrent Bronchiolitis and Pneumonia in early childhood.
- Cardinal features of respiratory allergy and infectious diseases.
- History of at least 3 episodes in last one year.

**Exclusion criteria:**

- Severe and Complicated respiratory allergic disorders those need hospitalization.
- Diagnosed C/o Tuberculosis
- Diagnosed C/o Pleural effusion
- Diagnosed C/o Emphysema
- Diagnosed C/o Lung abscess
- Diagnosed C/o Bronchiectasis
- Diagnosed C/o Pleurisy
- Diagnosed C/o Nasal polyps
Congenital lung/cardiac anomalies

Chronic debilitating diseases

**Discontinuation criteria:**
- Parents/guardian not willing to continue with the treatment.
- Patients develop a life-threatening complication during the treatment.
- Any other acute illness.
- The appearance of features of respiratory infections.

**Assessment criteria:**

**A. Clinical Assessment**
Assessment of the clinical symptoms depending on the severity is done according to the scoring pattern given below:

1. **Cough (Kasa)** –
   - No cough-0
   - Occasional cough-1
   - Continuous cough with moderate pain-2
   - Continuous cough with severe pain-3

2. **Rhinorrhea (Nasa Srava)** -
   - No Nasa Srava-0
   - Only in the morning-1
   - Morning and evening-2
   - Continuous- 3

3. **Nasal Obstruction (Ghranoparodha)**-
   - No obstruction-0
   - Only during sleep-1
   - Intermittent throughout the day-2
   - Complete obstruction throughout the day & night-3

4. **Impaired smell (Gandhagyan)**
   - Normal smell perception-0
   - Perceiving smell with difficulty-1
   - Perceiving only pungent smell-2
   - No smell perception-3

5. **Inflammation of throat (Galashotha)**
   - No sore throat -0
   - Sore throat with pain and no difficulty in food intake-1
   - Sore throat with pain and difficulty in food intake-2
   - Sore throat with pain which interferes the intake of liquids too-3

6. **Dyspnoea (Shwaskashtata)**
   - No dyspnea-0
   - Dyspnoea on cold exposure-1
   - Dyspnoea present and forced to take medicine for the relief-2
   - Dyspnoea not relieving even after medicine-3

7. **Nasal/eye itching (Nasa/Akshi Kandu)**
   - No itching-0
   - Occasional itching-1
   - Nasal itching only-2
   - Continuous Nasal/ eye itching-3

8. **Wheezeing (Sashabda Swaas)**
   - No Wheezing-0
   - Mild Wheezing-1
   - Severe Wheezing audible on auscultation not audible from outside-2
   - Wheezing audible even from outside-3

9. **Headache (Shirahshoola)**
   - No Headache-0
   - An occasional Headache only at the time of Pratishyaya-1
   - A frequent Headache but not severe-2
   - Severe constant Headache-3
10. Fever (Jwara)
- No fever-0
- Fever only at night-1
- Mild fever throughout the day-2
- High-grade fever throughout the day-3

11. Sneezing (Kshwathu)
- No Sneezing-0
- Sneezing only at the time of vyadhivegawastha-1
- Sneezing with mild reasons-2
- Always Sneezing-3

12. Hoarseness of voice (Swarasada)
- No Hoarseness of voice-0
- Hoarseness of voice only at the time of pratishyaya-1
- Hoarseness of voice present but no difficulty in speech-2
- Cannot make sounds due to the Hoarseness of voice-3

B. Objective assessment
A Peak Expiratory Flow Rate (PEFR) was measured in children above 7 years on every follow up i.e. after 15 days.

B Laboratory parameters
- Blood - (T.L.C, D.L.C, HB %, TEC, IgE) were measured before and after treatment.

Assessment of tolerability: Though the combinations under study were purely herbal in origin, close observation of patients using drugs included in the trial was done carefully for any untoward effects.

Analytical and statistical method to be used: The clinical efficacy of the drug was analyzed statistically on all the symptoms mentioned in the assessment criteria. Initially, the variation and significance of effect seen within all the patients were calculated by using Paired’t’ test. (Wilcoxon two-tailed for subjective parameters and for the objective parameters Paired’t’ test two-tailed) has been applied.

Intergroup Comparison is done by using unpaired t-test. (Mann Whitney-U Test) More specifically quantify the percentage of improvement in each patient was also calculated using the formula BT-AT/BTx100.

TRIAL DRUG: “Shirishadi Syrup” (A Hypothetical Ayurvedic Compound)

<table>
<thead>
<tr>
<th>Table No. II Ingredients Of Trial Drug Compound</th>
<th>[7],[8],[9],[10]</th>
</tr>
</thead>
<tbody>
<tr>
<td>S.N.</td>
<td>Name</td>
</tr>
<tr>
<td>1</td>
<td>Shirish</td>
</tr>
<tr>
<td>2</td>
<td>Shunthi</td>
</tr>
<tr>
<td>3</td>
<td>Marich</td>
</tr>
<tr>
<td>4</td>
<td>Pippali</td>
</tr>
<tr>
<td>5</td>
<td>Madhu (Honey)</td>
</tr>
</tbody>
</table>

Control drug: Lobodil Suspension (Salveo Pharmaceuticals)

Manufactured by- Surya Herbal Limited, Noida, India
Table No. III Composition Of Lobodil Suspension (One Tsf Of Powder Contains)

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name</th>
<th>Botanical Name</th>
<th>Amount present</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Talishpatra</td>
<td>Abies webbiana</td>
<td>0.32 gm</td>
</tr>
<tr>
<td>2.</td>
<td>Vasaka</td>
<td>Adhatoda vasica</td>
<td>1.56 gm</td>
</tr>
<tr>
<td>3.</td>
<td>Dalchini</td>
<td>Cinnamomum zeylanicum</td>
<td>0.15 gm</td>
</tr>
<tr>
<td>4.</td>
<td>Brihat ela</td>
<td>Amomum subulatum</td>
<td>0.15 gm</td>
</tr>
<tr>
<td>5.</td>
<td>Marich</td>
<td>Piper nigrum</td>
<td>0.62 gm</td>
</tr>
<tr>
<td>6.</td>
<td>Pippali</td>
<td>Piper longum</td>
<td>1.25 gm</td>
</tr>
<tr>
<td>7.</td>
<td>Ardraka</td>
<td>Zingiber officinale</td>
<td>0.95 gm</td>
</tr>
<tr>
<td>8.</td>
<td>Nisadal</td>
<td>-</td>
<td>0.15 gm</td>
</tr>
<tr>
<td>9.</td>
<td>Sugar</td>
<td>-</td>
<td>10.00 gm</td>
</tr>
</tbody>
</table>

Clinically proven drug for allergy and stress-induced asthma, common cold and cough.

Observation And Results:
The observations and results in the study are made on the basis of demographic, constitutional, and clinical profiles of 60 patients having respiratory allergic disorders. 08-10 years age group was the most (53.33%) affected group. Males (63.33%) were more prone to RADs as compared to females. Maximum (68.33%) patients were belonging to the Hindu community. Maximum numbers of cases were belonging to an urban area (76.66%) and middle socioeconomic status (61.66%). Overall incidences showed that Allergic Rhinitis (41.66) and mixed group (36.66%) followed by Allergic asthma (21.66%). Maximum number (46.66%) of cases exhibited seasonal manifestation of allergic rhinitis. Overall in 58.33% of cases, family history was present. Dust 48.33%, smoke (due to pollution) 45%, cold water 45%, cold air & seasonal changes 41.66% were the potential triggers. Overall Tonsillitis 55% otitis media 31.66% snoring & migraine 15% as associated complains. The overall incidence of characteristic allergic appearance were 36.66% allergic shiners, 30% with nasal crease, 25% allergic salute, allergic gape 5%, allergic cluck 3.33%. Kapha Vata Prakriti patients were found to be more (38.33%) prone for RADs. Maximum number (56.66%) of patients of the trial were under Mandagni. IgE level was found to be elevated in 83.33% and 80.00% in group A and B respectively. TEC level was found to be elevated in 73.33% and 76.66% in group A and B respectively.

Table no. IV showing statistical presentation of all symptoms after treatment in group A and group B

<table>
<thead>
<tr>
<th>S. N.</th>
<th>Symptoms</th>
<th>Group</th>
<th>Mean Score</th>
<th>Gain</th>
<th>S.D.</th>
<th>S.E.</th>
<th>P</th>
<th>Ipt</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>B.T.</td>
<td>A.T.</td>
<td>Diff</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Cough</td>
<td>A</td>
<td>1.90</td>
<td>1.16</td>
<td>0.73</td>
<td>38.59</td>
<td>0.44</td>
<td>0.08</td>
</tr>
<tr>
<td></td>
<td></td>
<td>B</td>
<td>1.80</td>
<td>1.10</td>
<td>0.70</td>
<td>38.88</td>
<td>0.46</td>
<td>0.08</td>
</tr>
</tbody>
</table>
2. Nasal discharge

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.86</td>
<td>1.23</td>
<td>0.63</td>
<td>0.0001</td>
<td>33.92</td>
</tr>
<tr>
<td>B</td>
<td>1.86</td>
<td>1.13</td>
<td>0.73</td>
<td>0.0001</td>
<td>39.27</td>
</tr>
</tbody>
</table>

3. Nasal obstruction

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.23</td>
<td>0.66</td>
<td>0.56</td>
<td>0.0001</td>
<td>45.96</td>
</tr>
<tr>
<td>B</td>
<td>1.20</td>
<td>0.56</td>
<td>0.63</td>
<td>0.0001</td>
<td>52.77</td>
</tr>
</tbody>
</table>

4. Impaired smell

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0.66</td>
<td>0.36</td>
<td>0.30</td>
<td>0.0001</td>
<td>44.99</td>
</tr>
<tr>
<td>B</td>
<td>0.63</td>
<td>0.33</td>
<td>0.30</td>
<td>0.0001</td>
<td>47.39</td>
</tr>
</tbody>
</table>

5. Throat inflammation

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.03</td>
<td>0.30</td>
<td>0.73</td>
<td>0.0001</td>
<td>70.95</td>
</tr>
<tr>
<td>B</td>
<td>0.93</td>
<td>0.30</td>
<td>0.63</td>
<td>0.0001</td>
<td>67.84</td>
</tr>
</tbody>
</table>

6. Dyspnoea

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.06</td>
<td>0.56</td>
<td>0.50</td>
<td>0.0001</td>
<td>46.86</td>
</tr>
<tr>
<td>B</td>
<td>1.03</td>
<td>0.50</td>
<td>0.53</td>
<td>0.0001</td>
<td>51.59</td>
</tr>
</tbody>
</table>

7. Nasal/eye itching

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.10</td>
<td>0.53</td>
<td>0.56</td>
<td>0.0001</td>
<td>51.51</td>
</tr>
<tr>
<td>B</td>
<td>1.16</td>
<td>0.66</td>
<td>0.50</td>
<td>0.0001</td>
<td>42.84</td>
</tr>
</tbody>
</table>

8. Wheezing

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.46</td>
<td>0.76</td>
<td>0.70</td>
<td>0.0001</td>
<td>47.71</td>
</tr>
<tr>
<td>B</td>
<td>1.03</td>
<td>0.46</td>
<td>0.56</td>
<td>0.0001</td>
<td>54.79</td>
</tr>
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</table>

9. Headache

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.43</td>
<td>1.03</td>
<td>0.40</td>
<td>0.0001</td>
<td>27.91</td>
</tr>
<tr>
<td>B</td>
<td>1.00</td>
<td>0.70</td>
<td>0.30</td>
<td>0.0001</td>
<td>30.00</td>
</tr>
</tbody>
</table>

10. Fever

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.53</td>
<td>1.23</td>
<td>0.30</td>
<td>0.0001</td>
<td>19.56</td>
</tr>
<tr>
<td>B</td>
<td>1.40</td>
<td>1.00</td>
<td>0.40</td>
<td>0.0001</td>
<td>28.57</td>
</tr>
</tbody>
</table>

11. Sneezing

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>1.26</td>
<td>0.80</td>
<td>0.46</td>
<td>0.0001</td>
<td>36.77</td>
</tr>
<tr>
<td>B</td>
<td>0.66</td>
<td>0.50</td>
<td>0.34</td>
<td>0.0001</td>
<td>52.30</td>
</tr>
</tbody>
</table>

12. Hoarseness of voice

<table>
<thead>
<tr>
<th>Group</th>
<th>Value 1</th>
<th>Value 2</th>
<th>Value 3</th>
<th>Statistic</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>0.73</td>
<td>0.40</td>
<td>0.33</td>
<td>0.0001</td>
<td>45.42</td>
</tr>
<tr>
<td>B</td>
<td>0.66</td>
<td>0.30</td>
<td>0.36</td>
<td>0.0001</td>
<td>55.00</td>
</tr>
</tbody>
</table>

Statistical evaluations of overall symptoms showed somewhat similar result in both the groups of patients. In cough, nasal discharge, nasal obstruction, throat inflammation, dyspnoea, nasal/eye itching, wheezing, headache, sneezing extremely significant improvement was seen in group A. Whereas in other symptoms such as impaired smell, fever, hoarseness of voice very significant improvement was seen in group A. In case of cough, nasal discharge, nasal obstruction, throat inflammation, dyspnoea, nasal/eye itching, wheezing, sneezing, fever, hoarseness of voice extremely significant improvement was seen in group B, whereas in impaired smell, headache very significant relief was seen. (Table no. IV)

After treatment the improvement % in Cough, Nasal discharge, Nasal obstruction, impaired smell, Throat inflammation, Dyspnoea, Nasal/eye itching, Wheezing, Headache, Fever, Sneezing and Hoarseness of voice in Group A were 38.59%, 33.92%, 45.96%, 44.99%, 70.95%, 46.86%, 51.51%, 47.71%, 27.91%, 19.56%, 36.77%, 45.42% respectively. After treatment the improvement % in Cough, Nasal discharge, Nasal obstruction, impaired smell, Throat inflammation, Dyspnoea, Nasal/eye itching, Wheezing, Headache, Fever, Sneezing and Hoarseness of voice in Group B were 38.88%, 39.27%, 52.77%, 47.39%, 67.84%, 51.59%, 42.84%, 54.79%, 30%, 28.57%, 52.30%, 55% respectively. (Table no. IV)
Statistical evaluations of laboratory parameters showed extremely significant results in Hb level, TLC, Neutrophil count, Eosinophil count, TEC and IgE level of both the groups and lymphocyte count showed the significant result in Group A and no significant result in group B. (Table No.V)

After treatment the improvement % in Hb%, TLC, Neutrophils, Lymphocytes, Eosinophil Count, TEC and IgE in Group A are 06.66%, 08.13%, 07.15%, 03.96%, 22.54%, 30.31%, 27.45% respectively. After treatment the improvement % in Hb%, TLC, Neutrophils, Lymphocytes, Eosinophil Count, TEC and IgE in Group B are 07.22%, 23.66%, 06.502%, 0.380%, 20.27%, 39.44%, 25.65% respectively. (Table No. V)

Table No. VI Overall Improvement In Clinical Features In Both Groups
Table No. VI showing overall assessment of improvement in clinical features after completion of clinical trial showed good improvement in 16.67% of clinical features, fair improvement in 75% of clinical features and poor (marginal) improvement in 8.33% of clinical features in Group-A. While in Group-B, 50% of clinical features showed good improvement in 16.67% of clinical features, fair improvement in 75% of clinical features and poor improvement in 75% of clinical features and rest 50% of clinical features showed fair improvement.

Discussion:

Discussion Regarding Mode Of Action Of Trial Drug

Respiratory allergic disorders or allergy of Pranavaha Srotas mainly involves Pratishayaya and Shuasa Roga caused due to allergy. As described earlier the Dosha involved is Vata and Kapha. Dushya involved is Rasa Dhatu and Srotas affected are Pranavaha, Annavaha, and Rasavaha. Thus, the drug selected should have the potency to act simultaneously on Pranavaha, Annavaha, and Rasavaha Srotas i.e., it should possess Deepana, Pachana, Vata Kapha Shamaka, and Srotoshodhaka properties. For this action, the drug should be Laghu, Sukshma, Ushna, Teekshna in Guna.

The compound drug “Shirishadi syrup” is the combination of drugs having Amapachaka (Shunthi, Marich, Pippali), Rasayana (e.g. Pippali), Vishaghna (e.g. Shirisha), Shothahara (eg. Shirisha, Pippali) and Shleshmahara (Pippali, Shunthi, Marich, Madhu), Juvarahara (Pippali) and Shulahara (Pippali, Shunthi), Vedana-Sthapan (Shirisha) properties.

The Study drug is having Katu, Tikta, Kashaya and Madhura rasa, Laghu, Ushna and Teekshna Guna and Katu Vipaka, Ushna Virya and Kapha Vata shamaka properties. It shows Srotoshodhaka properties which may possibly assist to eliminate sluggish Dosha in the Srotas.

Katu, Tikta and Kashaya rasa, Ushna virya, and Laghu, Ushna, Teekshna guna having the properties of Kapha-Vilayana, Pachana, Srotoshodaka. Due to this liquification of Kapha dosha takes place resulting in clearing of respiratory tract on coughing.

Most of the drugs have Vata Kapha Shamaka properties. Shirishadi syrup is having potential properties of all eviating both Vata and Kapha dosha by virtue of Tikta, Katu, Kashaya Rasa, and Ushna Virya, Laghu, Teekshna and Ushna quality. Thus, Kapha Shamaka properties of drug help in breaking the Srotorodha and digestion of Ama, which leads to proper functioning of the Agni.

Some ingredients of the study drug having Rasayana (immunomodulator) properties, which helps to improve Dhathu both qualitatively and quantitatively. (eg Piper longum.). Pippali is very good Rasayana for Pranavahasrotas which is the main site of manifestation of RAD.

The components of the study drug might have acted at various levels in breaking the pathogenesis of allergic disorders. Some hamper the immediate hypersensitivity reaction by inhibiting histamine release, or by inhibiting mast cell degranulation as for e.g. A.lebbeck, Piper longum depletes histamine from bronchial and lung tissues,[11],[12] Mast cell inhibitory activity is possessed by Piper longum.[12] On the other hand, some are effective for late phase allergy owing to the inhibitory action on leukotirole systems as or by reducing the eosinophil count. e.g. Pippali.[12]

The efficacy of the trial drug in reducing the nasal discharge is because of the Vata and Kapha Shamaka quality of the drug. The anti-allergic, anti-inflammatory and Rasayana effect of various ingredients is responsible for the overall relief in the symptoms, including nasal discharge, sneezing, itching etc. (e.g., Shirisha, Shunthi, Maricha, and Pippali).[12],[13]

A cough in RAD is mainly due to post-nasal dripping causing throat irritation. Improvement in a cough may be because of pacification of Vata and Kapha Dosha and removal of obstructing Kapha from the Pranavaha Srotas due to anti-tussive and mucolytic properties of the ingredients as Pippali[11],[14]

Relief from dyspnea and reduction in wheezing was
because of relieving the obstruction in the passage of Pranawayu by Samakapha. The probable action of the drug was because of its Kapha Vatahara effect and Ushna Teeksna Guna. The relief might be the result of bronchodilator action of Pippali, Shirisha.\[11,12\] and Spasmolytic action of Pippali acts by inhibiting the contractile action of histamine by glycoside saponin.\[13\] A. lebbek has potent mast cell stabilizing property also has antihistaminic effect by glycoside catechin.\[16\]

Nasal obstruction, throat inflammation, loss of smell and hoarseness of voice are because of edematous and later on inflammatory changes in various target organs in the disease process. The study drug showed significant anti-inflammatory effect. (e.g. Shirisha, Shunthi, Maricha, and Pippali).\[13,17,18,19\] Although as observed during the study that, very severe inflammation have shown lesser changes. Therefore, it may be suggested that the therapy may be continued further for the few more months.

A headache is mainly because of allergic sinusitis accompanying the RADs. Significant relief from a headache after treatment was observed which might be due to anti-inflammatory properties of Shirisha, Shunthi, Maricha, and Pippali.\[13,17,18,19\] Vata dosha get pacified and becomes responsible for the relief. Shunthi, Maricha, Pippali also proved to possess analgesic property.\[12,20,21\]

Mild inflammation due to allergic reaction showed marked relief. It may be because of proven anti-inflammatory activity of Shunthi, Maricha, and Pippali.\[17,18,19\]

Increased Hb % after treatment is suggestive of the effect of the trial drug in improving Rasa Dhatuagni owing to the effect of Shunthi, Maricha, Pippali and thereby the quality of Rakta dhatu. In addition, the drug has Amapachaka and Srotoshodhaka effect. Thus, by cleansing the channels and by increasing the absorption, it has improved the appetite and digestive power of the patients.

Improvement in the status of leucocyte count shows the anti-inflammatory activity of the trial drug. It may be attributed to immunomodulatory and its anti-inflammatory effect of various components such as Shirisha and Trikatu i.e. Shunthi, Maricha, Pippali.\[13,17,18,19\]

Eosinophil and IgE is suggestive of potent anti-allergic and anti-inflammatory activity of the study drug such as Shirisha and Trikatu.\[13,17,18,19\]

Increased PEFR is suggestive of the fact that, the trial drug could have modified the existing airflow limitation caused due to obstruction. Trikatu i.e. Shunthi, Maricha, Pippali have Deepana, Pachana, and Amadoshahara properties.\[22,23,24\] In addition, Madhu (honey) has Chhedana property. Thereby, the drug is helpful in restoring normal breathing. As Pippali acts as Rasayana on Pranvahasrotas, it may have worked on the quantitative and qualitative improvement of lung structure and function.

The insignificant change in the condition of the patient after follows up with respect to after treatment position is suggestive of the requirement of long-term therapy.

From this research work, it has been concluded that along with anti-allergic & bronchodilator effect, the immunomodulatory regimen will play a key role in future therapies for allergic respiratory diseases. These treatment modalities may not only treat allergic disease but also be beneficial in reducing the morbidity and mortality for which it is responsible.

Psychological stress may be an additional environmental factor that worsen the oxidative toxicity the ingredients like, Pippali by their anti-stress activity are responsible for the regression of symptoms.\[26\]

Thus, overall improvement in the condition of the patient of the study group may be because of the multidimensional properties of the drug. (Vatakaphahara, Deepana, Pachana, and Vatanulomana properties), which are essential for breaking down pathogenesis of RAD. The main factor in this disease as in many other diseases is Ama, and the Deepana-Pachana properties of the drug will digest the Ama by improving the Jatharagni as well as Rasagni and Bhutagni. Furthermore, the Sothahara
Karma of most of the contents will neutralize the Srotorodha in Pranavaha Srotasa due to Sotha created by Sama Vata.

**Conclusion**

Ayurveda can constitute a multidimensional approach for the treatment of RADs. It comprises of excellent drugs, Pathya Sevana, Nidan Parivarjana and Rasayana Sevana, which can be successfully used to deal with the RADs. Concisely, it can be concluded that the study drug “Shirishadi Syrup” and control drug “LOBODIL Susp.” both are somewhat equally effective in alleviating and reducing RADs in children. Prolongation of therapy for a few more months may provide more relief. No adverse effect, of the study drug, was observed during the study. As the study was conducted over a small group of patients, a similar study performed over a large sample for a longer duration could have presented much sharper and more accurate results. Further multicentric extensive study is needed to authenticate the results of the research work.

**References**


सारांश:

स्कूल जाने वाले बच्चों में स्वास्थ्य की अनूज्जात संबंधित रोग की व्यापकता भारत के विभिन्न रूपों में ५.२०% के बीच पायी गई है। इस रोग की व्यापकता में वृद्धि के पर्यावरणीय कारकों, आहार जनित विसंगतियाँ और दोषपूर्ण जीवन शैली को जिम्मेदार ठहराया जा सकता है।

व्यस्त अनूज्जात विकार (R.A.D.) में मुख्य रूप से शामिल है एलर्जीक अस्थमा और एलर्जीक रामनाइटिस। R.A.D. इस विकार को आयुर्वेद में कास प्रतिशाप एवं तमक व्यस्त के साथ सह संबंधित मान सकते हैं। इस बीमारी के निवारक पहलूओं में आयुर्वेद व्यक्तिगत अनुदी अवधारणा रहता है तथा विभिन्न उपचारों और व्यंजनों द्वारा इसे प्रभावित किया जा सकता है। इन तथ्यों को व्याख्या में रखते हुए एक यात्रिक नियंत्रण परीक्षण ६२ हफ्तों के लिए योजना बनाई गई जिसमें एक आयुर्वेदिक यौगिक शिरिशादी सीरप और एक स्थापित आयुर्वेदिक औषधि लोबोडील सर्पेंशन उन बच्चों को जो व्यस्त एलर्जी विकार (R.A.D) के साथ पीड़ित थे। उनमें शिरिशादी सीरप की प्रभावकारिता के ज्यादातर कारण कम करने के लिए दी गई। इस अध्ययन में व्यस्त एलर्जी विकार से प्रभावित बच्चों का आयु वर्ग ५ से १० साल निर्धारित कर एनआईए रणरण जयपुर के बाल रोग ऑपरी और आईपीडी विभाग से चयन किया गया था। अध्ययनार्थ चयनित कुल ६० मरीजों को दो समूहों में विभाजित कर प्रत्येक समूह में ३० रोगियों को आयोजित किया गया। गुप्त ए और गुप्त बी में क्रमशः शिरिशादी सीरप तथा एक स्थापित आयुर्वेदिक औषधि लोबोडील सर्पेंशन दिये गये। साखियावासी रूप से अधिकांश लक्षणों तथा प्रयोगशाला मानकों में अलग-था महत्वपूर्ण परिणाम दोनों समूहों में देखा गया था। साखियाबाहु यूनिफर्म के बाद यह निर्माण निकाला गया था कि दोनों दवाओं का R.A.D. के पूर्व लक्षणों में सुधार के संदर्भ में समान रूप से प्रभावी हैं। साथ ही इस औषध का अध्ययन के दौरान कोई दुष्परिणाम नहीं मिला।