A RANDOMIZED CONTROLLED CLINICAL STUDY ON THE EFFICACY OF CHITRAKAHARITAKI AVALEHA IN VATAJ PRATISHYAYA W.S.R. TO ALLERGIC RHINITIS IN CHILDREN”

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ABSTRACT: All the ultimate goals of life can be achieved only by a healthy individual with the healthy mind and body. The branch Kaumarabhrita mainly concerned with care of child. Vataj Pratishyaya which is a very common disease affecting any age group of both sex & prevalent worldwide was selected. ChitrakaHaritaki Avaleha was taken as a trial drug. In the present study total 68 number of patients were registered for the trial and were randomly distributed in two groups i.e. 30 students in group A, 30 students in group B were completed the course of treatment. The observations were recorded before and after study. Statistical tests were applied. Result drawn on the basis of statistical tests.

KEYWORDS: Vataj Pratishyaya, Allergic rhinitis, Nasasrawa, Chitrakaharitaki avaleha, Kashyapa samhita.

INTRODUCTION: The war between the health and disease starts with onset of life i.e. since childhood and to protect the healthy childhood, a proper management is needed which is provided by the one and only discipline i.e. Kaumarabhrita. Most of the symptoms present in vataj pratishyaya points towards the allergic rhinitis. It is a disease having nasal discharge, nasal obstruction, itching over the nose and sometimes over the eyes, sneezing and headache. ChitrakaHaritaki Avaleha was taken as a trial drug. It was prepared according to the granthokta method described in Bhaishajyaratnavali. It was administered orally to the patients in experimental group. To other group which was a control group, standard syrup preparation of cetirizine hydrochloride was given orally for seven days. Cetirizine hydrochloride is a standard drug of
modern science which is commonly used for allergic rhinitis.

In the present study total 68 number of patients were registered for the trial and were randomly distributed in two groups i.e. 30 students in group A, 30 students in group B were completed the course of treatment. The patients in group A received oral treatment with chitrakaharitaki Avaleha. The patients of group B received oral treatment with syp cetirizine hydrochloride. The general observations of the patients were plotted in the clinical study. Several technically skilled hands intervened in this work in each and every step. Maximum effort had been taken to avoid the bias. The observations were recorded on every follow up. The changes in the symptoms were recorded after and before treatment. The statistical test was applied. Result was obtained on the basis of statistical analysis.

MATERIALS AND METHODS

AIMS AND OBJECTIVES

AIM:
To evaluate the effect of CHITRAKAHARITAKI AVALEHA in Vataj Pratishyaya w.s.r. To allergic rhinitis in children.

OBJECTIVES:-
• To study the vataj pratishyaya according to Ayurveda and modern science.
• To study the recurrence of vatajpratishyaya in children.
• To study the effect of chitrakaharitaki avaleha in vataj pratishyaya.
• To study the adverse effect of chitrakaharitaki avaleha if any arises.

DISEASE REVIEW:-
To Know the Disease in its all respects is an important part of a clinical study. Before going to any treatment aspect one should know the disease clearly. The disease Pratishyaya is very broad that’s why it is very necessary to study it through different points of view including the modern medical science.

Defination:
Here Acharya give importance to Vata Dosha. Dalhana explained Pratishyaya as a codition in which Vata dominant Tridosha along with Rakta when afflicts the Nasa causes nasal discharge etc. and clinical features is terms as Pratishyaya.
Classification of Pratishyaya according to different Acharya is given in the table below.

<table>
<thead>
<tr>
<th>Acharya</th>
<th>Vataja</th>
<th>Pittaja</th>
<th>Kaphaja</th>
<th>Raktaja</th>
<th>Sannipataja</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kashyapa</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Charaka</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Sushruta</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Vagbhata</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

NIDANA

The term Nidana means “that which gives indication about a disease.” This term is also used for the cause of the disease as well as the diagnosis of the disease. Acharya Sushruta has given prime importance to Nidanaparivarjana in treatment mentioned in the uttartantra. Mandagni, Ajeerna, Vishamashan, Atijalapana, Ati Sheeta Ambu pana Guru, Sheeta, Madhura atisevan Viharaj Ati nariprasang Atiswapna Ratri Jaragana Sleep after Dugdhapana Ati parshwa shayana Vega sandharana Ati asru srava Ritu vaishamya Manasika Ati Krodha are the nidana of pratishyaya.

PURVARUPA

Before the actual onset of a disease, there are some symptoms develop that symptoms gives an idea or some clues about the upcoming disease such symptoms are called as Purvarupa. These are Shirogurutvam (Heaviness of the head), Kshavathu (Sneezing), Angamarda (Bodyache) Stambha (Stiffness in nose) Samanya Lakshanas - These are Shirahashoola, Shirogaurava, Jwara, Kas a, Swarabheda, Aruchi, Klam.

Lakshanas of Vataja Pratishyaya according to various Acharyas

<table>
<thead>
<tr>
<th>Lakshanas</th>
<th>Kashyapa</th>
<th>Charaka</th>
<th>Sushruta</th>
<th>Vagbhata</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tanunasa srava</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Nasavaro dha</td>
<td>+</td>
<td>-</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Shirahshoola</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Kshavathu</td>
<td>-</td>
<td>+</td>
<td>-</td>
<td>+</td>
</tr>
<tr>
<td>Osthashosha</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Swarabheda</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Talushosha</td>
<td>-</td>
<td>-</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Mukhhashosha</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>+</td>
</tr>
</tbody>
</table>

Upashaya:

- Oral intake of Ghrita. (warm) appropriate time.
- Various kinds of Swedana & Vamana.
Dhumapana & Gandusha should be done depending upon the types of Dosha involved.

Snigdha, Ushna, Lavana & Amla Padartha Sevana.

Anupashaya:

- Excessive intake of Guru, Madhura, Sheeta substance.
- Excessive intake of cold water.
- Dhul, Rajaha Sevana.
- Atidrava Sevana after meal.
- Vishamashana.

SAMPRAPTI

Concept of Etiopathogenesis

The process of the disease starts from the exposing of etiological factors in the body. They are either endogenous or exogenous. Some of them can be avoided by adopting proper precautionary measure some factors like Kala, Desa are mostly unavoidable. So as per as these factors are concerned the rest mechanism depends on the body resistance i.e. Vyadhiksamatva. If the vyadhiksamatva is high and the Dhatu, Srotasas, and Agni are functioning well the body fights against the etiological factors successfully, thereby maintaining its health. But when the etiological factors are stronger than the resistance power of the body they vitiate the Dosha and indirectly the Dusya also and the process of the disease starts. While explaining the Samprapti of Pratishyaya the following points are to be taken into consideration:

UPADRAVA: If the disease not diagnosed earlier or not treated properly it can lead to the complications. Those complications may lead to some life threatening events. So the complications may be studied while treating the disease. Acharya Sushruta states that all types of Pratishyaya leads to vitiated condition without proper treatment & give rise to following complications: Badhirya, Andhata, Kasa, Agnisada, Sha. These are the upadravas.

Chikitsa Sutra: On the basis of the above description we can formulate the following Chikitsa Sutra (line of treatment): Langhana, Gritapana, Swedana, Vamana, Avapida Nasya.
**Chikitsa of Vataja Pratishyaya**

<table>
<thead>
<tr>
<th>Upakramas</th>
<th>Charaka</th>
<th>Sushruta</th>
<th>Vagbhata</th>
<th>Chakradatta</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ghritapana</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>Shirovirechana</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
<tr>
<td>(Nasya)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Snigdha Dugdhapana</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mamsarasa</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dhumrapana</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Upanaha</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Niruha Basti</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

**Pathya**
- Avoid direct contact of wind (A. H. Ut. 20/1).
- Cover head, ear, nose with thick, warm cloths.
- Food containing Laghu, Ushna, Snigdha properties.
- Jangala Mansa, jaggery, milk.
- Trikatu, Yava, Godhuma, Masura, Munga, Dadima, Haritaki.
- Yushas or Kulattha.

**Apathya:**
- Cold water.
- Exposure to cold.
- Anger, stress, sorrow.

**Drug Review** - Avaleha is that form of drug delivery system in which absorption starts right from oral cavity. Avaleha due to its good palatability, wide therapeutic applicability was used since ancient period. The term drug is derived from the French word “Drogue” i.e. dry herb. According to W.H.O., the drug is “A substance used in the diagnosis, treatment, or prevention of a disease or as a component of a medication”. Drug is the very important factor of Chikitsa Chatushpada.

CHITRAKAHARITAKI AVALEHA

**Procedure of making the drug:** Chitraka haritaki Avaleha was prepared according to the *granthokta vidhi*. Kwath of Amlaki 2800 gms, Guduchi 2800 gms, Dasha Moola 2800 gms, Chitraka 2800 mgs is made. Guda 5600 gms is added to it. Stirred it in sufficient fire then Haritaki (3584 gms) is added till it become semi solid. Then Trikatu, Trijataka 168 gms each is added. Then 28 gms of Yava Ksara is add on cooling of its own, 448 gms of honey was added to this at the end.
**Chitrakaharitaki Avaleha - Physiochemical Analysis**

1) **Loss on drying**
   - Chitraka Haritaki Avaleha: 15.86%

2) **Ash content**
   - Chitraka Haritaki Avaleha: 10.56%

3) **pH**
   - Chitraka Haritaki Avaleha: 5.72 pH

4) **Acid soluble matter**
   - Chitraka Haritaki Avaleha: 1.06%

5) **Water soluble extractive**
   - Chitraka Haritaki Avaleha: 24%

6) **Alcohol soluble extractive**
   - Chitraka Haritaki Avaleha: 17%

**CLINICAL STUDY:**

**PLAN OF STUDY:**

- **Grouping of the patients:**
  The patients who fulfilled the criteria of Vataj Pratishyaya were divided randomly into two groups.

- **Group A (Experimental group):**
  The patients in this group were treated by **CHITRAKAHARITAKI AVALEHA** orally.

- **Group B (Control group):**
  The patients in this group were treated by **CETIRIZINE HYDROCHLORIDE** orally.

**DETAILS OF DRUG ADMINISTRATION:**

<table>
<thead>
<tr>
<th></th>
<th>Group A (Experimental Group)</th>
<th>Group B (Control Group)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug Name</strong></td>
<td>Chitrakaharitakiavaleha.</td>
<td>Cetirizine hydrochloride.</td>
</tr>
<tr>
<td><strong>Time of</strong></td>
<td>After meals in 3 divided doses.</td>
<td>After meals O.D.</td>
</tr>
<tr>
<td><strong>administration</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Duration</strong></td>
<td>7 days.</td>
<td>7 days.</td>
</tr>
<tr>
<td><strong>Follow up</strong></td>
<td>7th, 15th, 21th day.</td>
<td>7th, 15th, 21th day.</td>
</tr>
</tbody>
</table>
**Doses of chitrakaharitaki:**

It is given to the patients of group A according to the granthokta matra. In Sharangadhara samhita it is mentioned that the matra of child of 1 year should be one “Masa”. This is near about 1.5 Gms. And it should be increased by one masa by each year completed by the child. Therefore it is increased according to that. It was given into divided doses.

**Doses of Cetirizine hydrochloride:**

The dose of cetirizine hydrochloride in children is given in many authentic books. As per as the mg/kg dose is concerned it can be given 0.2mg/kg body wt. But in nelson textbook of paediatrics the dose is given properly.2-5 yrs- dose given is 2.5 mg once in a day. It can be given maximum upto 5 mg/day depending on the severity. For age group above 6 the dose given is 5 mg/day. For this age group considering all the factors and severity of infection it can be given maximum upto 10 mg/day. So for this study the dose of this drug is calculated considering these all factors and intensity of the infection to the patient.

**CRITERIA FOR ASSESSMENT:-**

- Improvement in the patient was assessed mainly on the basis of changes in signs and symptoms of the disease as per gradation.
- Patients follow up was conducted on 7\textsuperscript{th}, 15\textsuperscript{th} and 21\textsuperscript{th} day.

**The gradations of the symptoms were as follows:**

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Grade 0</th>
<th>Grade 1</th>
<th>Grade 2</th>
<th>Grade 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasasrava (Rhinorrhea)</td>
<td>No nasal discharge.</td>
<td>Occasional discharge with visible fluid.</td>
<td>Discharge which needs mopping but controllable.</td>
<td>Severe discharge with fluid needs repeated mopping.</td>
</tr>
<tr>
<td>Kshavathu (Sneezing)</td>
<td>No sneezing.</td>
<td>1-10 sneezing/day</td>
<td>10-15 sneezing/day</td>
<td>More than 15 sneezing/day</td>
</tr>
<tr>
<td>Nasakandu (Itching in nose)</td>
<td>No itching.</td>
<td>Mild.</td>
<td>Moderate.</td>
<td>Severe which makes patient to rub always</td>
</tr>
<tr>
<td>Shirahshool (Headache)</td>
<td>No headache.</td>
<td>Mild headache doesn’t hamper activity of the child.</td>
<td>Moderate headache hampering activity of the child.</td>
<td>Severe headache making child severe irritable.</td>
</tr>
</tbody>
</table>
FOLLOW UP STUDY: - Follow up was conducted on 7\textsuperscript{th}, 15\textsuperscript{th} and on 21\textsuperscript{th} day.

OVERALL ASSESSMENT OF THE RESULT: -
At the end of the study, by using following parameters, assessment was obtained.

<table>
<thead>
<tr>
<th>Status</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cured</td>
<td>100% improvement in signs and symptoms</td>
</tr>
<tr>
<td>Markedly improved</td>
<td>75% or more improvement in signs and symptoms</td>
</tr>
<tr>
<td>Moderately improved</td>
<td>50% or more improvement in signs and symptoms</td>
</tr>
<tr>
<td>Mildly improved</td>
<td>25% or more improvement in signs and symptoms</td>
</tr>
<tr>
<td>Not cured</td>
<td>Less than 25% improvement in signs and symptoms</td>
</tr>
</tbody>
</table>

OBSERVATIONS AND RESULT

Total 68 patients were registered for the study of \textit{Vataja Pratishyaya} Distribution of patients was as follows:

<table>
<thead>
<tr>
<th>Group</th>
<th>Completed</th>
<th>Drop out</th>
<th>Total registered</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>30</td>
<td>6</td>
<td>36</td>
</tr>
<tr>
<td>B</td>
<td>30</td>
<td>2</td>
<td>32</td>
</tr>
</tbody>
</table>

- **Age wise distribution of patients of \textit{Vataja Pratishyaya} (Allergic Rhinitis):**

<table>
<thead>
<tr>
<th>Age (Yrs)</th>
<th>Group A</th>
<th>Group B</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>3-6</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>8.3%</td>
</tr>
<tr>
<td>6-9</td>
<td>5</td>
<td>18</td>
<td>23</td>
<td>38.33%</td>
</tr>
<tr>
<td>9-12</td>
<td>13</td>
<td>10</td>
<td>23</td>
<td>38.33%</td>
</tr>
<tr>
<td>12-14</td>
<td>9</td>
<td>0</td>
<td>9</td>
<td>15%</td>
</tr>
</tbody>
</table>

- **Sex wise distribution of patients of \textit{Vataja Pratishyaya} (Allergic Rhinitis):**

<table>
<thead>
<tr>
<th>Sex</th>
<th>Group A</th>
<th>Group B</th>
<th>Total</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>21</td>
<td>18</td>
<td>39</td>
<td>65%</td>
</tr>
<tr>
<td>Female</td>
<td>9</td>
<td>12</td>
<td>21</td>
<td>35%</td>
</tr>
</tbody>
</table>

- **Nasasrawa wise distribution of patients of \textit{vataja pratishyaya}:**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Day 1</th>
<th>Day 7\textsuperscript{th}</th>
<th>Day 15\textsuperscript{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gr A</td>
<td>Gr B</td>
<td>Gr A</td>
</tr>
<tr>
<td>3</td>
<td>24</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>4</td>
<td>2</td>
<td>6</td>
</tr>
<tr>
<td>1</td>
<td>0</td>
<td>0</td>
<td>22</td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td>5</td>
<td>2</td>
</tr>
</tbody>
</table>

- **Sneezing (\textit{Kshavathu}) wise distribution of patients of \textit{Vataja Pratishyaya} (Allergic Rhinitis):**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Day 1</th>
<th>Day 7\textsuperscript{th}</th>
<th>Day 15\textsuperscript{th}</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gr A</td>
<td>Gr B</td>
<td>Gr A</td>
</tr>
<tr>
<td>3</td>
<td>3</td>
<td>3</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>14</td>
<td>20</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td>1</td>
<td>20</td>
</tr>
</tbody>
</table>
• Nasal obstruction (*Nasavarodha*) wise distribution of patients of *Vataja Pratishyaya* (Allergic Rhinitis)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Day 0</th>
<th>Day 7th</th>
<th>Day 15th</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>5</td>
<td>6</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>1</td>
<td>1</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>0</td>
<td>16</td>
<td>10</td>
<td>23</td>
</tr>
</tbody>
</table>

• Itching in nose (*Nasakandu*) wise distribution of patients of *Vataja Pratishyaya* (Allergic Rhinitis)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Day 1</th>
<th>Day 7th</th>
<th>Day 21th</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Gr A</td>
<td>Gr B</td>
<td>Gr A</td>
</tr>
<tr>
<td>3</td>
<td>7</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>17</td>
<td>17</td>
<td>3</td>
</tr>
<tr>
<td>1</td>
<td>4</td>
<td>4</td>
<td>13</td>
</tr>
<tr>
<td>0</td>
<td>2</td>
<td>7</td>
<td>14</td>
</tr>
</tbody>
</table>

• *Shirahshool* wise distribution of patients of *Vataja Pratishyaya* (Allergic Rhinitis)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Day 1</th>
<th>Day 7th</th>
<th>Day 15th</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>4</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>2</td>
<td>15</td>
<td>14</td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>5</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>0</td>
<td>6</td>
<td>9</td>
<td>25</td>
</tr>
</tbody>
</table>

• Cardinal symptoms wise distribution

  - *Nasavarodha* - Total 34 number of patients i.e. 56.66% had *Nasavarodha* at first day.
  - *Nasasrawa* - Total 53 number of patients i.e. 88.33% had *Nasasrawa* at first day.
  - *Nasakandu* - Total 51 number of patients i.e. 85% had *Nasakandu* at first day.
  - *Kshavathu* - Total 57 number of patients i.e. 95% had *Kshavathu* at first day.
  - *Shirahshool* - Total 45 number of patients i.e. 75% had *shirahshool* at first day.

Chi square Table for *Nasasrawa*:

<table>
<thead>
<tr>
<th>Day</th>
<th>Chi Square value</th>
<th>Table value</th>
<th>Overall result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>4.30708</td>
<td>3.84</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>7th</td>
<td>26.559</td>
<td>5.99</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>15th</td>
<td>10.588</td>
<td>3.84</td>
<td>p &gt; 0.05</td>
</tr>
</tbody>
</table>
statistically the trial drug *chitrakaharitaki avaleha* is effective.

- **Chi square Table for *Kshavathu***

<table>
<thead>
<tr>
<th>Day</th>
<th>Chi Square value</th>
<th>Table value</th>
<th>Overall result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>505286</td>
<td>7.82</td>
<td><em>p &lt; 0.05</em></td>
</tr>
<tr>
<td>7th</td>
<td>0.16172</td>
<td>3.84</td>
<td><em>p &lt; 0.05</em></td>
</tr>
<tr>
<td>15th</td>
<td>3.15</td>
<td>3.84</td>
<td><em>p &lt; 0.05</em></td>
</tr>
</tbody>
</table>

For *Kshavathu* control drug cetirizine hydrochloride is more effective than *chitrakaharitaki avaleha*. (*p < 0.05*)

- **Chi square Table for *Nasavarodha***

<table>
<thead>
<tr>
<th>Day</th>
<th>Chi Square value</th>
<th>Table value</th>
<th>Overall result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>5.04692</td>
<td>7.82</td>
<td><em>p &lt; 0.05</em></td>
</tr>
<tr>
<td>7th</td>
<td>1.65</td>
<td>3.85</td>
<td><em>p &lt; 0.05</em></td>
</tr>
<tr>
<td>15th</td>
<td>5.4546</td>
<td>3.85</td>
<td><em>p &gt; 0.05</em></td>
</tr>
</tbody>
</table>

For *Nasavarodha* trial drug *chitrakaharitaki avaleha* is effective. The chi square value is significant as mentioned above. (*p > 0.05*)

- **Chi square Table for *Nasakandu***

<table>
<thead>
<tr>
<th>Day</th>
<th>Chi Square value</th>
<th>Table value</th>
<th>Overall result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>7.2778</td>
<td>7.82</td>
<td><em>p &lt; 0.05</em></td>
</tr>
<tr>
<td>7th</td>
<td>12.1</td>
<td>3.85</td>
<td><em>p &gt; 0.05</em></td>
</tr>
<tr>
<td>15th</td>
<td>5.4586</td>
<td>3.85</td>
<td><em>p &gt; 0.05</em></td>
</tr>
</tbody>
</table>

For *Nasakandu* the chi square value is significant (*p > 0.05*) trial drug *chitrakaharitaki avaleha* is effective.

- **Chi square Table for *Shirahshool***

<table>
<thead>
<tr>
<th>Day</th>
<th>Chi Square value</th>
<th>Table value</th>
<th>Overall result</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>3.225</td>
<td>3.85</td>
<td><em>p &lt; 0.05</em></td>
</tr>
<tr>
<td>7th</td>
<td>5.4546</td>
<td>3.85</td>
<td><em>p &gt; 0.05</em></td>
</tr>
</tbody>
</table>

For *shirahshool* trial drug *chitrakaharitaki avaleha* is effective because the chi square value is significant. (*p > 0.05*) on 7th day. On 15th day almost all the patients relieved from *shirahshool*.

- **Effect on cardinal symptoms of gr. A**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>BT</th>
<th>AT</th>
<th>Relief %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasasrawa</td>
<td>24</td>
<td>6</td>
<td>75%</td>
</tr>
<tr>
<td>Kshavathu</td>
<td>28</td>
<td>10</td>
<td>64.28%</td>
</tr>
<tr>
<td>Nasavarodha</td>
<td>14</td>
<td>7</td>
<td>50%</td>
</tr>
<tr>
<td>Nasakandu</td>
<td>28</td>
<td>16</td>
<td>42.85%</td>
</tr>
<tr>
<td>Shirahshool</td>
<td>24</td>
<td>5</td>
<td>87.5%</td>
</tr>
</tbody>
</table>

- **Effect on cardinal symptoms of gr. B**

Effect on cardinal symptoms of gr. B- Highly significant result was obtained in the symptom *Nasasrawa* i.e. 72%. *Kshavathu* was relieved by 86.20%. *Nasavarodha* was relieved by 90%. *Nasakandu* was relieved by 78.26%. Shirahshool was relieved...
by 85.71%. As cetirizine hydrochloride is a standard drug of modern science it also has significant result in all the symptoms.

- **Overall effect of Chitrakaharitaki Avaleha**

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Chi square value</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nasasrawa</td>
<td>26.559</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Kshavathu</td>
<td>3.15</td>
<td>p &lt; 0.05</td>
</tr>
<tr>
<td>Nasavarodha</td>
<td>5.456</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Nasakandu</td>
<td>12.1</td>
<td>p &gt; 0.05</td>
</tr>
<tr>
<td>Shirahshool</td>
<td>5.456</td>
<td>p &gt; 0.05</td>
</tr>
</tbody>
</table>

- **Overall effect of therapy** – Marked improvement was found in 16.67% in group A. Moderate improvement was observed in 53.33% in group A. Mild improvement was observed in 30%. Every patient’s symptoms have improved with variations. So there was not a single patient who shown no change in any symptom. No patient had complete remission in this group.

- **Effect of therapy in Recurrence:**

<table>
<thead>
<tr>
<th>Recurrence</th>
<th>Gr. A</th>
<th>%</th>
<th>Gr. B</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Present</td>
<td>5</td>
<td>16.67%</td>
<td>16</td>
<td>53.33%</td>
</tr>
<tr>
<td>Absent</td>
<td>25</td>
<td>83.33%</td>
<td>14</td>
<td>46.67%</td>
</tr>
</tbody>
</table>

- **Recurrence Of the disease:**

Group A: Recurrence was found in total 5 patients in this group i.e. 16.67%. Group B: Recurrence was found in total 16 patients in this group i.e.53.33 %. Recurrence of the disease was very high in group B as compared to group A.

- **Discussion about the selection of problem:**

Vataja Pratishyaya (Allergic rhinitis) is one of the most common diseases among all the age groups specially affecting the children. Nowadays childrens are also get affected by this disease. If the disease is not treated properly can lead to chronic stage and several Complications.

- **Discussion about the Disease Review:**

Vataj Pratishyaya is described by various Acharya through all the classics. These all classics have their detailed descriptions, classifications, symptomatologies, complications and management written in the Samhitas. Allergic
Rhinitis is a disease which makes the child physically and mentally irritable due to the symptoms like headache, sneezing and continuous rhinorrhea, nasal obstruction. Due to infection there is inflammation of mucous membrane.

- **Discussion on selection of treatment modality:**
  Following points need better consideration during the treatment fixation. Allergic rhinitis must be regarded as a serious condition, because it can impact negatively on the quality of life of sufferers not only by producing severe symptoms but also by producing complications. So it makes the child irritable.
  Drug should be easy to administer in children, promote the immunity of the patient, should promote the physical and mental health of the patient, which will prevent the recurrence of the disease.

- **Discussion on Drug Review:**
  It is also a challenge for the practitioner of balaroga to select the method of administration and the form of the medicine to be given to the child. Because the children are less cooperative in the treatment modality. Patients of pediatric age group don’t accept the dosage form of medicine ‘Kwatha’. So, taking the aspect of palatability with effective consideration the drug was administered in Avaleha form. Acharya Kashyapa has given importance to this Kalpana and has described a separate chapter *Leha Adhyaya in Sutra Sthana*.

- **Details of each constituent drug of Chitraka Haritaki Avaleha:**
  The main components of the preparation are Chitraka and Haritaki as the name suggested Chitraka Haritaki Avaleha. Chitraka has the basic properties to digest the Ama and also is the drug of choice for Deepana Pachana. Chitraka has Katu Vipaka and Ushna Veerya these properties help in digesting the viscous Kapha. The other drug is Haritaki. Haritaki contains five Rasas except Lavana with Kashaya predominance. It has inherent properties for absorption of secretion in the body. It also helps in bringing the Vayu downward. The other combination drug helps to give resultant action in Vataja Pratishyaya.

* Amlaki, Guduchi are the well known drugs for rejuvenation.

**Discussion on clinical study:**
- **The general observations of patients were as follows:**
  Total 68 patients were registered in the present study, which were divided
into 2 groups Group A and Group B, 8 patients left the treatment i.e. 6 in group A and 2 in Group B in.

- **Age:** Maximum number of patients i.e. 38.33% were from the age group 6-9 and 9-12 years, while 8.3% of patients were from the age group 3-6 years. The patients of age group 12-14 were 15%. The distribution is made taking completed age in consideration.

- **Sex:** Maximum number of patients i.e. 65% were Male, while 35% were Female.

- **Nasal discharge:**
  - **Group A:** Maximum number of patients i.e. 24 patients were reported grade 3 nasal discharge. 4 patients were reported grade 2 nasal discharge. Nasal discharge was absent in 2 patients.
  - **Group B:** Maximum number of patients i.e. 23 patients were reported grade 3 nasal discharge. 2 patients were reported grade 2 nasal discharge. Nasal discharge was absent in 5 patients.
  - Both the groups- In both the groups total 53 patients were reported nasal discharge.

- **Kshavathu wise distribution of patient:**
  - **Group A:** Maximum number of patients i.e. 14 patients were reported grade 2 Kshavathu. 11 number of patients were reported grade 1 Kshavathu .3 patients were reported grade 3 Kshavathu. Kshavathu was absent in 2 patients.
  - **Group B:** Maximum number of patients i.e. 20 patients were reported grade 2 Kshavathu. 6 number of patients were reported grade 1 Kshavathu .3 patients were reported grade 3 Kshavathu. Kshavathu was absent in 1 patient.
  - Both the groups- In both the groups total 57 patients were reported Kshavathu.

- **Nasal obstruction:**
  - **Group A:** Total 8 patients were reported grade 2 Nasavarodha. 5 number of patients were reported grade 3 Nasavarodha .1 patient was reported grade 1 Nasavarodha. Nasavarodha was absent in 16 patients
  - **Group B:** Total 8 patients were reported grade 2 Nasavarodha. 6 number of patients were reported grade 1 Nasavarodha.6 patients were reported grade 3 Nasavarodha. Nasavarodha was absent in 10 patient.
Both the groups- In both the groups total 34 patients were reported nasavarodha.

**Nasakandu:**

**Group A:** Total 17 patients were reported grade 2 Nasakandu. 7 number of patients were reported grade 3 Nasakandu. 4 patients were reported grade 1 Nasakandu. Nasakandu was absent in 2 patients.

**Group B:** Total 17 patients were reported grade 2 Nasakandu. 4 number of patients were reported grade 1 Nasakandu. 2 patients were reported grade 3 Nasakandu. Nasakandu was absent in 7 patients.

Both the groups- In both the groups total 51 patients were reported nasakandu.

**Shirahshool wise:**

**Group A:** Total 15 patients were reported grade 2 Shirahshool. 4 number of patients were reported grade 3 Shirahshool. 5 patients were reported grade 1 Shirahshool. Shirahshool was absent in 6 patients.

**Group B:** Total 14 patients were reported grade 2 Shirahshool. 6 number of patients were reported grade 1 Shirahshool. 1 patients was reported grade 3 Shirahshool. Shirahshool was absent in 9 patient.

Both the groups- In both the groups total 45 patients were reported shirahshool.

**Cardinal symptoms wise distribution**

**Nasasrawa:** Total 53 number of patients i.e. 88.33% had Nasasrawa at first day.

**Kshavathu:** Total 57 number of patients i.e. 95% had Kshavathu at first day.

**Nasavarodha:** Total 34 number of patients i.e. 56.66% had Nasavarodha at first day.

**Nasakandu:** Total 51 number of patients i.e. 85% had Nasakandu at first day.

**Shirahshool:** Total 45 number of patients i.e. 75% had Shirahshool at first day.

**Discussion on effect of therapies on cardinal symptoms:**

**Effect on cardinal symptoms of Chirtakaharitaki Avaleha:** Highly significant result was obtained in the symptom Nasasrawa i.e. 75%. It is also gives positive results statistically. The chi square value is significant. (p > 0.05) Kshavathu was relieved by 64.28%. But statistically it is less significant. (p < 0.05) Nasavarodha was relieved by 50%. It is also gives positive results.
statistically. The chi square value is significant. \( p > 0.05 \) Nasakandu was relieved by 42.85%. It is also gives positive results statistically. The chi square value is significant. \( p > 0.05 \) Shirahshool was relieved by 87.5%.

- **Effect on cardinal symptoms of Cetirizine Hydrochloride**
  - Highly significant result was obtained in the symptom Nasasrawa i.e. 72%. Kshavathu was relieved by 86.20%. Nasavarodha was relieved by 90%. Nasakandu was relieved by 78.26%. Shirahshool was relieved by 85.71%.
  - These all symptoms also gives positive results statistically \( (p > 0.05) \).

- **Total effect of Chitrakaharitaki Avaleha:**
  - Marked improvement was found in 16.67% in group A. Moderate improvement was observed in 53.33% in group A. Mild improvement was observed in 30%. Every patients symptoms has improved with variations. So there was not a single patient who shown no change in any symptom. No patient had complete remission in this group.

  - Effect of Chitrakaharitaki Avaleha was statistically significant as \( p > 0.05 \) for NasaSrava and nasakandu, Nasavarodha, as well as shirahshool. It is less Significant compared to control group for Kshavathu.

- **Effect of therapy in Recurrence**
  - **Group A:**
    - Recurrence was found in total 5 patients in this group i.e. 16.67%.
  - **Group B:**
    - Recurrence was found in total 16 patients in this group i.e. 53.33 %.
  - Recurrence of the disease was very high in group B as compared to group A.

**CONCLUSIONS**

The conclusions drawn on the basis of the study are presented below:

- Allergic rhinitis can be correlated with the Vataja Pratishyaya due to similarities in the signs and symptoms.
- Maximum number of patients i.e. 38.33% were from the age group 6-9 and 9-12 years, while 8.3% of patients were from the age group 3-6 years.
The patients of age group 12-14 were 15%.

- Maximum number of patients i.e. 65% were Male, while 35% were Females.
- Maximum number of patients i.e. 63.33% were from the Lower middle class. 16.66% of patients were from the middle class. While 20% were from poor class.
- *Nasasrawa* was relieved by i.e. 75%. It also shows significant result (p > 0.05) in group A.
- *Kshavathu* was relieved by 64.28%. But statistically it is less significant (p<0.05) in group A.
- *Nasavarodha* was relieved by 50%. It also shows significant result statistically (p>0.05) in group A.
- *Nasakandu* was relieved by 42.85%. It shows significant result statistically (p>0.05) in group A.
- *Shirahshool* was relieved by 87.5%. Statistically is gives significant result (p>0.05) in group A.
- None of the patient had complete remission, Marked improvement was found in 16.67% i.e. 5 patients. Moderate improvement was observed in 53.33% i.e 16 patients. Mild improvement was observed in 30% i.e. 9 patients in Group A. So there was not a single patient who shown no change.

- The *Chitrakaharitaki Avaleha* has given positive results because statistically it is significant in *Nasasrawa*, *Nasakandu*, *Nasavarodha* and *shirahshool*. Statistically the less effect is observed for *Kshavathu*.
- In control group i.e. Group B, Highly significant result were obtained in the symptom *Nasasrawa* i.e. 72%. *Kshavathu* was relieved by 86.20%. *Nasavarodha* was relieved by 90%. *Nasakandu* was relieved by 78.26%. *Shirahshool* was relieved by 85.71%. It shows the significant result for all the symptoms statistically (p>0.05).
- Recurrence was found in total 5 patients in group A i.e. 16.67% while in group B it is found in 16 patients i.e. 53.33%.

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A RANDOMIZED CONTROLLED CLINICAL STUDY ON THE EFFICACY OF CHITRAKAHARITAKI AVALEHA IN VATAJ PRATISHYAYA W.S.R. TO ALLERGIC RHINITIS IN CHILDREN


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