Pre and Post test Clinical study to evaluate the Immunomodulatory effect (IgE) of Virecana followed by Citrakaharitaki Leha in Allergic Asthma

Research Article

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Abstract

Allergic Asthma is one among the diseases which imposes a great burden on the subjects by hampering the quality of life of patients, reducing productivity, and causing work absence. The literary search hinted that there are no published works reporting both clinical and immunological(IgE) outcomes in Allergic Asthma. So the present study was a pre and post test clinical study to evaluate the effect of Ayurvedic line of management in inducing both immunological(IgE) and clinical outcomes in Allergic Asthma. In this study 30 patients were administered classical Virecana Karma (drug induced purgation) followed by Shamanoushadi (internal medicine) for 30 days. Statistical Analysis was done using SPSS VER. 20. Wilcoxon signed rank test was used to evaluate the Subjective parameters, in order to interpret the time of significant change. For objective parameters Paired Samples t- Test was used to evaluate the difference of significant change. The results showed improvement in the subjective criteria, objective criteria and the overall effect of the therapy with the exception of no statistically significant results in immunomodulatory (IgE) effect which proves that the particular management protocol adopted is found to be clinically efficent but not effective in inducing changes at the immune level.

Key Words: Allergic Asthma, Ayurveda, Virecana, Citrakaharitaki Leha, Tamaka Svasa.

Introduction

In this modern era of increasing pollution rates and toxicity in everything that is used by the mankind there is an increasing rise of Allergic Disorders all over the world. The burden of Allergic diseases in India has been on an uprising trend in terms of prevalence as well as severity. Allergic diseases comprise of Asthma, Rhinitis, Anaphylaxis, Drug, Food, Insect allergy, Eczema, Urticaria and Angioedema. Approximately 20% to 30 % of total population suffers from at least one of these Allergic diseases in India (1). Allergic Asthma is one among such diseases which imposes a great burden on the subjects afflicted by it. The cause for the increased burden is due to the change in lifestyle, increasing pollution index in cities that is associated with increased urbanization and presence of hazardous chemicals in air water and food.

Allergic Asthma is the most easily recognized Asthma phenotype, which often commences in childhood and is associated with a past and/or family history of Allergic disease such as Eczema, Allergic rhinitis, or food or drug Allergy (2).

Prevalence of Asthma varies considerably within countries and between countries. It is more prevalent in developed countries than developing ones, more in children (15%) than adults (10% to 12%), more in urban than rural areas, reasons of which are not fully understood. Nearly 8% to 10% of the total world population suffers from it. In India, the prevalence of Asthma has been found to be around 7% in the majority of surveys done. However, it has been reported to vary from 2% to 17% in different study populations (3). This disease causes economic burden, hampers the quality of life, productivity, efficiency and causes work absence among subjects. As it affects mostly the younger population it effects their career and future. The current available medical management has some shortcomings and limitations (4). So, Researchers are in critical need for drugs that would minimize the disease process.

Ayurveda is a traditional medicine that is being practiced in India and now gaining popularity worldwide. Ayurvedic basic theory is moulded upon the foundation formed by the three Doshas (Biological humors) which are Vata (biological air humor), Pitta (biological fire humor) and Kapha (biological phlegm humor). The etiopathogenesis and symptoms of Allergic Asthma lies very close to the entity Tamaka Svasa (Allergic Asthma) in terms of Ayurvedic classics. Tamaka Svasa and its management has been very widely explained in classical Ayurvedic texts like Caraka Samhita, Susruta Samhita and Ashtanga Hridaya. It is a Kapha –Vata Pradhan, Pitta Sihana Samudbhavajanya Vyadhi (originating from the site of biological fire humor). Vata getting obstructed due to...
the aggravated Kapha causing its Pratiloma Gati (retrograde movement) and in turn leading to the symptoms of Tamaka Svasa. The treatments explained include Sneha (oleation), Sveda (fomentation), Yamana (drug induced vomiting), Dhupana (fumigation) in the Vagavastha (acute stage) and Virecana in the Avegavastha (in remission). The Cikitsa (treatment) which is administered should be Kapha -Vata Hara (alleviating air and fire humor), Ushna (hot in potency) and Vatanulomaka (normalising air humor) (5). So Sodhana Cikitsa (purificatory therapy) combined with Samana Cikitsa (pacificatory therapy) could be better in managing Tamaka Svasa. The literary search hinted that there are no previous published Ayurvedic works on Allergic Asthma. Clinical outcomes combined with immunological outcomes of our therapeutic protocols in Allergic Asthma has also not been evaluated. So this was an effort to analyse the effect of Sodhana Cikitsa followed by Samana Cikitsa in producing immunomodulatory (IgE) effect along with clinical outcomes in cases of Allergic Asthma.

The present study is an open label, pre and post test clinical study. 30 patients diagnosed with Allergic Asthma after considering the inclusion and exclusion criteria were included in the study. Patients who belonged to the mild and moderate overall severity of Allergic Asthma, free from attacks were included in the study. As this condition is characterised by Alpa Kapha Avastha (reduced phlegm humor), Virecana Karma is the better choice of Sodhana Karma before the administration of Samanoushadhi. The patients were administered Ama Pacana (optimising digestion) with Trikatu Curnam (fine powder of dry drugs) (6) followed by Snehapana (intake of ghee in increasing quantities) with Shatpala Ghrita (medicated ghee) (7) for a maximum of 7 days followed by Sarvangha Abyangha Bhaapha Sveda (full body massage and steam bath) with Tila Taila (sesame oil) added with Saindhava Lavana (rock salt) for three days and Virecana was administered with Abhayadi Modakam (herbal purgative) (8) on the third day morning. After Samsarjana Karma (diet following purgation) patient was administered 10 grams of Citrakaharitaki Lehya (medicated linctus) (9) twice daily in divided doses as internal medicine for a period of one month.

Aims & Objectives
• To evaluate the immunomodulatory effect (IgE) of Virecana followed by Citrakaharitaki Lehya in Allergic Asthma.
• To evaluate the effect of Virecana followed by Citrakaharitaki Lehya in reducing the signs and symptoms of Allergic Asthma.
• To evaluate the effect of this treatment protocol in improving Pulmonary function (P.E.F.R)

Hypothesis
• Null Hypothesis, h0- Virecana followed by Citrakaharitaki Lehya is not effective in producing immunomodulatory effect (IgE) in Allergic Asthma.
• Alternate Hypothesis, h1 - Virecana followed by Citrakahareetaki Lehya is effective in producing immunomodulatory effect (IgE) in Allergic Asthma

Materials and Methods
Selection of Patient
For this study 30 number of patients with classical signs and symptoms of mild to moderate Allergic Asthma free from attacks were selected based on inclusion and exclusion criteria and registered after confirming diagnosis from the OPD and IPD of Kayacikitsa (internal medicine dept) department, Amrita School of Ayurveda, Kollam, Kerala. Ethical clearance was obtained prior to the recruitment of patients.

Diagnosis
Diagnosis was confirmed through detailed history taking, clinical examinations including Respiratory assessments and supporting laboratory investigations were done in addition. After proper diagnosis case was filled up in the clinical case proforma specially designed for the present study.

Inclusion Criteria
• Either gender and age group of 20 -60 years.
• Patients having classical signs and symptoms of Allergic Asthma of mild to moderate nature coming in between attacks according to GINA 2015 criteria (10).
• Patients having raised Serum IgE levels.
• Patient fit for Snehapana, Svedana and Virecana Karma.

Exclusion Criteria
• Status Asthmaticus and Acute Asthma cases were excluded.
• Age group: less than 20 years & exceeding 60 years are to be excluded.
• Any pre-diagnosed cases of Allergic Asthma associated with cardiovascular pathology.
• Severe Bronchial Asthma cases, Pulmonary Tuberculosis and Diabetes Mellitus.
• Pregnant Women & lactating mothers.
• Patients with other major Lung pathologies and unfit for Snehapana and Virecana Karma.
• Discontinuation of the treatment protocol.

Laboratory & radiological investigations
To exclude other disorders and for proper diagnosing following investigations were be done wherever necessary
• Hb%, TC, DC, ESR, R.B.S,
• Routine urine, Stool examination,
• Chest x ray, Mantoux test,
• E.C.G, U.S.G Abdomen

Criteria for assessment (11)
Subjective Criteria
Breathlessness, Wheezing, Cough, Expectoration of sputum, Overall Severity, No of Asthma Attacks /2 weeks.
Grading of Subjective criteria (11)

The following grading pattern was adopted.

- Breathlessness: Absent-0, Mild-1, Moderate-2, Severe-3
- Wheezing: Absent-0, Mild-1, Moderate-2, Severe-3
- Cough: Absent-0, Mild-1, Moderate-2, Severe-3
- Expectoration of sputum: Absent-0, <2.5ml/day-1, 2.5-15ml/day-2, 15-25ml/day-3
- Overall Severity: Absent-0, Mild intermittent-1, Mild persistent-2, Moderate persistent-3
- Number of Asthma attacks/2 weeks: Absent-0, 1-2 times-1, 3-4 times-2, 5-6 times-3

Objective criteria

- Haematological investigations
  - Serum Immunoglobulin E (S. IgE)
  - Absolute Eosinophil Count (AEC)

Assessment of Lung function
- Peak Expiratory Flow Rate (P.E.F.R)

Assessment of Asthma control
- Asthma Control Test (A.C.T). (10)

Evaluation of overall clinical effect of therapy

Evaluation of overall clinical effect of therapy was analysed based on the overall severity parameter before and after treatment as it includes clinical symptoms, lung function and exacerbation of Asthmatic attacks

Complete therapeutic intervention

<table>
<thead>
<tr>
<th>S.NO</th>
<th>Procedure</th>
<th>Drug</th>
<th>Dose</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pancakarma procedures (Purificatory therapy)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1</td>
<td>Purva Karma (Pre-operative procedures)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ama Pachanam</td>
<td>Trikatu Curnam</td>
<td>5 grams twice daily before food</td>
<td>4-5 days or till the appearance of Nirama Lakshanas (features of proper digestion)</td>
</tr>
<tr>
<td></td>
<td>Snehapanam</td>
<td>Shatpala Ghrita</td>
<td>Ascending dose according to p/h digestion</td>
<td>7 days or till appearance of Samyak Snigdha Lakshanas (features of proper oleation)</td>
</tr>
<tr>
<td></td>
<td>Sarvangha Abhyangha &amp; Bashpa Sveda</td>
<td>Lavanayukta Tila Tailam</td>
<td>3 days</td>
<td>45 minutes</td>
</tr>
<tr>
<td>1.2</td>
<td>Pradhana Karma (Main purificatory therapy)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Virecanam</td>
<td>Abhayadi Modakam</td>
<td>1-2 tablets according to Koshta (G.I tract)</td>
<td>1 day</td>
</tr>
<tr>
<td>1.3</td>
<td>Paschat Karma (Post operative procedures)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peyadi Krama (diet following purgation)</td>
<td></td>
<td></td>
<td>Acc to Sudhi (assessment of purification based on no of bouts of purgation)</td>
</tr>
<tr>
<td>2</td>
<td>Oral medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Samanoushadi</td>
<td>Citrakaharitaki Leha</td>
<td>5 grams twice daily before food</td>
<td>30 days</td>
</tr>
<tr>
<td>3</td>
<td>No: Of Patients – 30</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Assessment</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Subjective assessment
- Breathlessness
- Wheezing
- Cough
- Sputum expectoration
- Overall severity
- No of Asthma attacks/2 weeks

Objective assessment
- Serum IgE
- Absolute Eosinophil Count
- PEAK EXPIRATORY FLOW RATE (P.E.F.R)
- Asthma Control Test (A.C.T)

Statistical Analysis

Statistical analysis was done using SPSS VER. 20. Completed 30 patients were taken for statistical analysis. Wilcoxon signed rank test was done on subjective parameters, to interpret the time of significant change. For objective parameter Paired Samples t-Test was done for analysing the difference of significant change.
Observations
The clinically significant observations are tabulated below.

Table 2: Showing Observations on the subjects

<table>
<thead>
<tr>
<th>Age - 20-29 yrs</th>
<th>Religion – Hindu</th>
<th>Occupation –Jobs other than white collar and labourers</th>
<th>Exposure to triggering factors like dust, smoke and pollen</th>
<th>Inhabitation – rural</th>
<th>Appetite- regular</th>
<th>Bowel – 1-2 times/day</th>
<th>Prakruti (body type acc to Ayurveda) - Vata Kapha</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>86.7%</td>
<td>43.3%</td>
<td>46.7%</td>
<td>96.7%</td>
<td>73.3%</td>
<td>70%</td>
<td>43.3%</td>
</tr>
</tbody>
</table>

Results
Statistical significances along with the overall effect of interventions on study parameters before and after treatment are as follows.

All the subjective parameters like breathlessness, wheezing, cough, sputum expectoration, overall severity and number of Asthma attacks were highly significant (p<0.0001). All objective criteria’s like Asthma Control Test, P.E.F.R and A.E.C were highly significant (p<0.0001). Serum IgE was found to be insignificant (p>0.05).

Evaluation of overall clinical effect of therapy
Evaluation of overall clinical effect of therapy was analysed based on the overall severity parameter as it includes clinical symptoms, lung function and exacerbation of Asthmatic attacks.

Before treatment out of the 30 patients included in the study 7 patients came under the severity mild intermittent in which the symptoms were very mild.

23 patients came under the severity mild persistent.

There were no patients under the severity moderate persistent.

Grading of Asthma overall severity of patients before treatment
Table 5: Showing no of patients coming under respective overall severity parameters before treatment

<table>
<thead>
<tr>
<th>Grade of Asthma overall Severity BT</th>
<th>No of patients BT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Absent</td>
<td>0</td>
</tr>
<tr>
<td>Mild Intermittent</td>
<td>7</td>
</tr>
<tr>
<td>Mild Persistent</td>
<td>23</td>
</tr>
<tr>
<td>Moderate persistent</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
</tr>
</tbody>
</table>

Grading of Asthma overall severity of patients after treatment
Table 6: Showing no of patients coming under respective overall severity parameters after treatment

<table>
<thead>
<tr>
<th>Grade of overall severity AT</th>
<th>No of patients AT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild Intermittent relieved to absence of symptoms</td>
<td>7</td>
</tr>
<tr>
<td>Mild Persistent relieved to mild intermittent</td>
<td>23</td>
</tr>
<tr>
<td>Total</td>
<td>30</td>
</tr>
</tbody>
</table>

So from the above analysis suggests that 7 patients who had mild or trace, intermittent clinical presentations showed marked improvement after treatment and the rest 23 who had mild persistent clinical presentations showed moderate improvement after treatment.
Discussion

Allergic Asthma is a clinical condition characterized by shortness of breath, wheezing, cough and or tightness of the chest. These clinical features point to the involvement of Prana Vaha Srotas (respiratory tract). Variations in the rate and pattern of breathing are indicated in Dushiti (vitiation) of Prana Vaha Srotas. The clinical presentation of Allergic Asthma indicates vitiation of Vata and Kapha Doshas. The pathology involving allergy or the predisposing atopy indicate a Pitta association in this disease. The condition varies in presentations of severity, viz. mild, mild intermittent, mild persistent, moderate persistent and severe persistent. This suggests difference in Amshamsa Dosha (variation in humors) relation in each stage. Every stage will have a different proportion of Vata–Kapha involvement.

Tamaka Svasa is a variety of Svasa Roga (Asthma) with Kapha Dosha predominance. Udzbhavasthana (site of origin) of this clinical condition is mentioned as Pittasthana or Adho Amasaya (duodenum). The specific Samprapti (pathogenesis) mentioned explains that there is a Pratiloma Gati of Vata by the obstructed Kapha resulting in the manifestation of this disease. Pragvyata (wind) and Sleshmala Ahara (phlegm aggravating foods) may be indicators of allergens which precipitate the disease. With the above short discussion we could say that Allergic Asthma could be thought of in the lines of Tamaka Svasa in Ayurvedic literature (12).

Discussion on disease

Exposure to dust, smoke and various particulate matter was observed as the perpetuating and precipitating factors in Allergic Asthma patients of this study. Coir workers, cashew workers, salesmen etc were the study subjects. Rajas (dust) and Dhuma (smoke) exposure had been listed in the Svasa Nidana (etiology of Asthma) which initiates the disease process. It also aggravated the presenting illness. These may be the allergens that trigger the hypersensitivity type-1 reaction resulting in Asthma. The above said occupation also paved way to the constant exposure of some type of particulate matter. This also would trigger the immune mechanism ending in the disease.

All the clinical features of Allergic Asthma were present in varying severity in all individuals of the study. This indicates the inherent atopy in the individuals. The varying severity may be due to the varying levels of sensitivity to the triggering factors. Most of the patients were coming under the mild intermittent and mild persistent categories of Asthma.

The serum IgE levels varied from 259 IU/ml to 5027IU/ml to start with. The maximum value of AEC noted in the included population was 1000 cells/cu mm. These high values are indicators of abnormal immune response. This may be due to the accumulation of Malarupa Kapha (phlegm humor in waste form) or Pitta in Rasa Dhatus (first body tissue according to Ayurveda). It could be either understood as Ama or Kledamsa (metabolic toxins/ wastes) in the circulation. That is why the treatment started with Ama Pachana and then Kleda Nirharana (removal of metabolic wastes) through Virecana.

In this study 50% patients had episodes of running nose, sneezing, and recurrent episodes of upper respiratory tract infections prior to the manifestation of the cardinal symptoms of Asthma. 40% of the patients were having allergic symptoms since childhood and few years later they were found to have symptoms of Asthma. This shows the slow and gradual progression of type-1 hypersensitivity towards the airways. These observations point to the relevance of past history in this clinical condition. Most of the patients reported that episodes of fever and upper respiratory tract worsened the conditions. It is in lieu to the triggering factors mentioned in the literature. Deviated nasal septum was seen in 50% of patients in this study. Jae-Cheul et al concluded that a significant association was found between obstructive nasal septum disease and asthma (13).

A Pranavaha Srotodushhti Vikara with Svasa and Kasa (cough) as its main symptom is a Yapya Vyadh (manageable). It is Sadhya (curable) if it is acute in onset. The Samprapti could be understood as;

Figure 1 - Samprapti of Pranavaha Srotodushhti Vikara

Discussion on drug review

In this study, Trikatu Curna was used for Ama Pacana, Shatpala Ghrita for Snehapana, Abhayadi Modaka for Virecana and Citrakaharitaki Leha for Vyadhi Samana.

Probable mode of action of medicines

Probable mode of action of Trikatu Curnam

Mandagni and Ama formation initiates the Samprapti in Tamaka Svasa. So Trikatu Curna which contains Pippali, Marica and Nagar are given for Dipana- Pacana (optimising digestion) as the first line of management. It corrects the Agni and ensures proper Rasa Dhatu formation. Dipana drugs kindles the gastric fire but do not help in digesting the undigested food where as Pacana drugs are those which cook the
undigested food but do not kindle the appetite. So by the combined effect of both these drugs make sure that the Ahara Paka (digestion) is proper and Sara Bhaga (essence) of Rasa Dhatu is formed properly. This reduces the over accumulation of Malarupa Kapha-Pitta or Kledamsa. As Tamaka Svasa is a Vata-Kapha predominant disease this will help in breaking the initial part of the basic Vyadhi Samprapati (14). Moreover Trikatu (fine powder of dried drugs) has a bioavailability enhancing action on other medicaments (15).

Mode of action of Snehapana

The mode of action of Snehapana can be explained as follows

Here Snehapana is administered as a Purvakarma of Virecana. In Tamaka Svasa the Dushti (vitiation) is at the level of Koshta. The Sneha plays an important role in Utkleshana (excitement) of the Koshtasthita Dosha. The Snehana Karma also brings Anulomana (normalising) to the Pratiloma Vata, the major culprit in the pathogenesis (16).

Mode of action of Bhaskha Svedana

Svedana Dravya (drugs used for sudation) has its main actions like Stambhagna (removes stagnation), Gouravagna (removes heaviness), Sitagna (alleviates ailments due to cold) and Sveda Karaka (sweat inducing). The mode of action can be explained as Srotoshodhana (clearing body channels) and Vata Niyama (normalising air-humor) - Svedana therapy induces Srotoshodhana. Proper Svedana that is administered after Snehapana helps to regulate the Vata Dosha. It is very important as Vata and Kapha are the main factors responsible for the causation of Tamaka Svasa. As a result of opening the Sveda Granthi (sweat pores) and regulating the action of Vata Dosha, stagnant Mala (metabolic wastes), Sveda and other toxins get eliminated out and Srotosudhi (clarity of channels) is attained. As in Tamaka Svasa there is Sangha (obstruction) to Vayu by the vitiated Kapha Dosha in the Srotas, this helps in bringing normal movement of Vayu in the Srotas.

Agni Dipana - Ushna and Tikshna (penetrating) properties of Svedana Karma helps in Pacana of Ama Dosh, which result in stimulation and normal functioning of Agni. It ensures that proper Paka of Akara occurs and Dhaturarpana (bodily tissue formation) is intact. As in Tamaka Svasa there is increased production of Malarupi Kapha which is the Kitta Bhaga (waste part) of improperly formed Rasa Dhatu, for which the basic cause is Jataragni Mandyata (reduced digestion) and subsequent Ama Dosh, this Agni Dipana helps in breaking the basic Samprapti (17).

Mode of action of Virecana

Virecana is the therapeutic process by which the liquefied and Koshtagata Doshha (humors in GIT) are forcibly expelled through the anal route.

Action of Virecana Karma can be explained as follows.

In this disease where we have compared Allergic Asthma with that of Tamaka Svasa, Virecana would be working in such a way that it removes the Dushita Pitta from the Pitta Sthana and also it causes removal of the liquefied Kapha Doshha and brings Anulomana of Vata facilitating its normal functioning (18).

The action of Virecana as per modern basis

In this study Virecana was administered with Abhayadi Modakam which is basically a Stimulant purgative due to the presence of Trivrit and Danti in it. Mode of action of stimulant purgatives can be explained as follows.

Stimulant Purgatives

They are powerful purgatives: often produce gripping. They irritate the intestinal mucosa and thus stimulate motor activity. Some of them do primarily increase motility by acting on myenteric plexuses, the more important mechanism of action is accumulation of water and electrolytes in the lumen by altering absorptive and secretory activity of the mucosal cell. They inhibit Na+K+ATPase at the basolateral membrane of villous cells-transport of Na+ and accompanying water into the interstitium is reduced. Secretion is enhanced by activation of cAMP in crypt cells and by increased PG synthesis. Larger doses of stimulant purgatives can cause excess purgation, fluid and electrolyte imbalance. Hypokalaemia can occur on regular use. Subacute or chronic intestinal obstruction is another contraindication (19).

Asthma & GERD

GERD can be a compounding factor in the pathogenesis and development of Asthma. Not only is the asthmatic patient more likely to have GERD as compared to the general population, but also GERD is recognized as a potential trigger in many cases of severe Asthma. Several mechanisms have been implicated by which GERD may exacerbate the Asthma. Two mechanisms are important in understanding this exacerbation of Asthma.

• Oesophageal acid stimulates vagally mediated tracheobronchial responses, and this increases the bronchial hyper-responsiveness to other stimuli.
• By irritating sensitive asthmatic airways following micro-aspiration of even tiny refluxed material into the tracheobronchial tree, which contributes to the adverse airway effects.

So it can be understood that Virecana helps in removing the excess oesophageal acid reflux thereby reducing chances for Asthma exacerbation due to acid reflux as it works mainly on Pitta Dosha and at the Pitta Sthana (20).

Mode of action of Citrakaharitaki Lehya

Citrakaharitaki Lehya - The pharmacological properties of Citrakaharitaki Lehya are as follows:

Katu, Tikta Rasa (bitter and pungent in taste) predominant; Laghu, Ushna, Ruksha Guna (light, hot and dry by nature) predominant; Ushna Virya (hot in
Discussion on effect of therapies

Effect of therapy on subjective parameters

- **Effect on shortness of breath-** There was a relief of 58% in shortness of breath after treatment. It was found to be significant at (P value< 0.0001). It could be due to that fact that after *Virecana* and *Samanoushadi*, the airway hyperresponsiveness to allergens could have reduced probably thereby preventing microvascular leakage, inflammation and subsequent bronchoconstriction which leads to shortness of breath.

- **Effect on wheezing-** There was a relief of 62.22% in wheezing after treatment. It was found to be significant at (P value< 0.0001). It could be due to the same mechanism explained for shortness of breath that after *Virecana* and *Samanoushadi* the airway hyperresponsiveness to allergens could have reduced probably thereby preventing microvascular leakage, inflammation and subsequent bronchoconstriction which leads to narrowing of airways which cause wheezing.

- **Effect on cough-** There was a relief of 73.91% in cough after treatment. It was found to be significant at (P value< 0.0001). Most of the patients included in this study were having mild scores of cough and the treatment would have brought mucolysis in the airways resulting in reduction of cough which is a reflux mechanism to remove the mucous secretions which could be the probable cause for the relief.

- **Effect on expectoration of sputum-** There was a relief of 62.0% in expectoration of sputum after treatment. It was found to be significant at (P value< 0.0001). It could be due to the same mechanism explained for cough that *Virecana* and *Samanoushadi* would have brought mucolysis in the airways resulting in reduction of sputum expectoration.
Effect of therapy on objective parameters

- **Effect on number of Asthma attacks-** There was a relief of 56.82% in number of asthmatic attacks after treatment. It was found to be significant at (P value< 0.0001). It could be due to that fact that after **Virecana** and **Samanoushadi** the airway hyperresponsiveness to allergens could have reduced probably thereby preventing chances of initiating a type I hypersensitivity reaction which is the prime initiator of an Asthmatic attack thereby reducing the number of Asthma Attacks in total.

- **Effect on Asthma Control Test-** There was a relief of 81.12% in Asthma control test after treatment. It was found to be significant at (P value< 0.0001). As there is reduction in number of Asthma attacks, increase in quality of life, reduced work absence, Asthma Control Test rises automatically.

- **Effect on Peak Expiratory Flow Rate (P.E.F.R) -** There was a relief of 83.51% in P.E.F.R after treatment. It was found to be significant at (P value< 0.0001). It could be due to that fact that after **Virecana** and **Samanoushadi** the airway mucus hypersecretion and oedema should have reduced probably and there could be minimal dilatation of airways thereby increasing air intake and Lung function.

- **Effect on serum Immunoglobulin E-** There was 19.96% relief in serum IgE. But there was no statistically significant difference between the mean IgE before treatment and after treatment (P value > 0.05). IgE levels were reducing but not up to a significant level. The probable cause could be the short time period of intake of post **Virecana** and less number of medicines post **Virecana**. It can be inferred that the allergic immunoglobulin could be taking more time for its reduction in serum and also a minor exposure to the triggering factors could have contributed to its rise in serum.

- **Effect on Absolute Eosinophil Count (AEC)-** There was a relief of 18.25% in AEC after treatment. It was found to be significant at (P value< 0.0001). Eosinophils being a major inflammatory cell in Allergic Asthma as there is reduced action of pre inflammatory mediators, the eosinophil infiltration could have reduced after the whole treatment protocol.

Conclusion

So based on the observations and critical analysis following conclusions have been derived.

- Patients of Allergic Asthma coming under the mild to moderate category can be compared to that of **Tamaka Svasa** on basis of clinical presentation and can be managed on the lines of **Tamaka Svasa Cikitsa** explained in **Ayurvedic Texts**.

- **Virecana** followed by **Citrakaharitaki Leha** was found to be significant in producing clinical outcomes and increasing P.E.F.R.

- **Virecana** followed by **Citrakaharitaki Leha** was found to be not significant in producing immunomodulatory effect (IgE) in Allergic Asthma.

- Thus based on the observations made in the clinical study the alternate hypothesis is rejected and null hypothesis is accepted i.e. **Virecana** followed by **Citrakaharitaki Leha** is not effecting in producing immunomodulatory effect in Allergic Asthma.

Limitations and recommendations

Compact and final conclusions cannot be made due to small sample size and the short study period.

Follow up was not done and the post treatment status of the patients could not be assessed with regards to the sustained relief.

The study can be repeated with a larger sample size and longer study duration

As **Kapha Dosha** is one of the main culprit behind the pathogenesis of the disease, its **Visishta Cikitsa** (specific treatment) ie, **Vanama Karma** can be administered prior to **Virecana** to evaluate whether the results are better when compared to **Virecana** alone.

The reason for insignificant immunological outcomes could be due to the lesser duration of treatment protocol and less number of medicines post **Virecana**. If there were more **Samanoushadi** after treatment the results would have been better.

More studies should be done to evaluate the effect of other **Ayurvedic** treatments at the Immune levels with the help of more parameters.

References

11. Shyam Prasad M, Evaluation of the role of Nithyavirechana and Nayapayam kashaya in...


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