

Effectiveness of *Shadbindu Taila Pratimarsha Nasya* Along with *Ghrit Bhrisht Haridra* in *Vataja Pratishyaya* (Allergic Rhinitis): A Randomized Open Label Clinical Study

Research Article

Senthiya Preeti¹, Charu Bansal^{2*}, Shukla Umesh³, Zainab Saleha⁴

1. Assistant Professor, Veena Vadini Ayurveda College Bhopal. MP. India.

2. Professor, 4. Assistant Professor, P.G. Department of Swasthavritta & Yoga,

3. Principal, Head P.G. Department of Panchakarma,

Pt. Khushilal Sharma Govt. Ayurveda College & Institution, Bhopal M.P. India.

Abstract

Allergic Rhinitis has been recognized as global health problem which impairs quality of life and work efficiency of the person. It is an IgE mediated inflammation of nasal mucosa caused by allergen. Aim: Combined efficacy of the *Shadbindu Taila Pratimarsha Nasya* along with oral administration of *Ghrit Bhrisht Haridra powder* (Cow ghee roasted *Curcuma longa* L.) compare with oral administration of *Ghrit Bhrisht Haridra powder* alone in the management of *Vataja Pratishyaya* (Allergic Rhinitis). Material and Methods: This was randomized, open label clinical study. Randomly selected 60 patients of *Vataja Pratishyaya* were randomly divided into two groups (30 in each group). Allergic Rhinitis was assessed based on TNSS score, ESR and AEC. Group A patients were treated with combine therapy while Group B were advised to take only *Ghrit Bhrisht Haridra powder* for 45 days. Statistical analysis used: Relief in the symptoms were assessed in percentage and result were assessed by signed-ranks test, Mann Whitney, paired and unpaired 't' test. Results: In group 'A' patients, 12.04% decrease in ESR was reported with ($p < 0.0001$), while in group B only 3.57% decrease in ESR reported with ($p = 0.0029$). Relief observed in Group 'A' on symptoms Rhinorrhoea, Nasal Itching, Nasal Obstruction and Sneezing were 73.66%, 94.74%, 86.90%, 88.15% respectively compare to 47.56%, 38.05%, 54.24%, 44.16% in Group 'B' with ($p < 0.0001$) in both groups. Conclusion: Study suggested use of combined *Ayurvedic* therapy (*Shadbindu Taila Pratimarsha Nasya* along with oral administration of *Ghrit Bhrisht Haridra powder*) as therapeutic measure for *Vataja Pratishyaya*.

Key Words: *Curcuma longa*, Allergic Rhinitis, Turmeric, *Pratimarsha Nasya*, Ayurvedic Nasal drug administration.

Introduction

Over 400 million people are suffering with allergic rhinitis all over the world and ranked fifth as most common chronic disease and usually continues throughout life (1). It affects social life, sleep, school and work. Around 20 -30% of the Indian Population is suffering with allergic rhinitis and 15% developed asthma (2). It is an IgE mediated inflammation of nasal mucosa caused by allergen. It presents with four cardinal symptoms of Rhinorrhoea, Nasal obstruction, Nasal itching and Sneezing. And also causes sleep disturbance, fatigue, depressed mood and cognitive function, that impairs daily life activity (3). Symptoms of allergic rhinitis had been found to be similar with

symptoms of *Vataja pratishyaya* such as *Tanusrava* (rhinorrhoea), nasal itching, nasal obstruction, headache and sneezing (4). Long-lasting or untreated allergic rhinitis can lead to sinus and ear infections due to inflammation and swelling. Ayurveda also consider that untreated *Pratishyaya* can convert into *Dushta Pratishyaya* and can cause deafness, blindness, anosmia, eye diseases, cough and *Shoth* (inflammation) (5). Contemporary medicine was found to be able only to reduce its severity for short time hence, the present study had been planned to find out the effects of *Shadbindu Taila Pratimarsha Nasya* along with *Ghrita Bhrista Haridra*.

Aim and Objectives

To find out the effect of *Shadbindu Taila Pratimarsha Nasya* and oral administration of *Ghrit Bhrisht Haridra* in the management of *Vataja Pratishyaya* (Allergic Rhinitis).

- To evaluate the combined efficacy of the *Shadbindu Taila Pratimarsha Nasya* along with oral administration of *Ghrit Bhrisht Haridra* (*curcuma longa* powder roasted with cow-ghee) in the management of *Vataja Pratishyaya* (Allergic Rhinitis).

* Corresponding Author:

Charu Bansal

Professor,

P.G. Department of Swasthavritta & Yoga,

Pt. Khushilal Sharma Government Ayurveda College & Institution,

Bhopal M.P., India.

Email Id: bansalcharu73@rediffmail.com

- To evaluate the efficacy of oral administration of *Ghrith Bhrisht Haridra* alone in the management of *Vataja Pratishyaya* (Allergic Rhinitis).

Materials & Methods

Study Design

This study was designed as open label randomized control clinical study.

Selection of the Patients

Total 70 patients irrespective of caste, religion and socioeconomic status who were diagnosed to have *Vataja Pratishyaya* (Allergic Rhinitis) were randomly selected from the out-patient Department and inpatient Department of Kayachikitsa, Panchakarma and Swasthavritta of Pt. Khushilal Sharma Govt. (autonomous) Ayurveda College and Hospital, Bhopal. Then in single day out among 70 healthy volunteers 60 healthy volunteers were selected randomly by simple random lottery method and distributed randomly in equal numbers (n = 30 in each group) in Group A and Group B. Among these patients 4 patients of group B were discontinued the study due to their personal reasons.

Ethical Clearance

The study was started after approval from the Institutional Ethics Committee with Ref. No/SL/IEC/2018/SV-14 Bhopal dated 12/05/ 2018. Written informed consent was obtained from patients prior to inclusion in the study.

Diagnostic criteria

Patients was diagnosed on the basis of the signs & symptoms of *Vataja Pratishyaya* (Allergic Rhinitis) and Peripheral Eosinophil Count, ESR and AEC. A clinical proforma was prepared containing detailed sign & symptoms of disease and required essential investigations.

Inclusion criteria

- Patients with cardinal signs & symptoms of *Vataja Pratishyaya* (Allergic Rhinitis), belonging to either sex, between the age group of 20 to 60 years and ready to give written consent form were included in the study.

Exclusion criteria

- Patient suffering from Hypertrophic Rhinitis, Atrophic Rhinitis, Rhinitis Sicca, Chronic systemic disease like T.B., D.M, Cardiovascular disease, known cases of bronchial asthma, nasal polyp, otitis media, orthodontic problems, nasal surgery, nasal carcinoma, severe DNS cases, mentally retarded subjects, pregnant & lactating women and those were smokers and alcoholics were excluded.
- *Dushta Pratishyaya* patients were also excluded.

Grouping and Posology

- **Group A:** This group was assigned with 30 *Vataja Pratishyaya* (Allergic Rhinitis) patients and were

treated with combine therapy *Shadbindu Taila Pratimarsha Nasya* along with 5 grams of *Ghrith Bhrisht Haridra* (*curcuma longa L.* powder roasted with cow-ghee) orally with luke warm water daily in morning for 45 days. *Nasya* procedure was carried out in morning and evening times. Quantity of oil which got after the finger dipped in oil up to the second metacarpophalangeal joint was considered as daily dose of *Pratimarsha Nasya* for each nostril.

- **Group B:** This group assigned 30 *Vataja Pratishyaya* (Allergic Rhinitis) patients and were advised 5 grams of *Ghrith Bhrisht Haridra* (*curcuma longa L.* powder roasted with cow-ghee) orally with luke warm water daily in morning for 45 days.

Duration of Study

The duration of study was 45 days.

Trial Drug Details

The ingredients of *Shadbindu Taila* and *Haridra* (*curcuma longa L.*) dry rhizome were obtained from Vindhya herbal (Miner forest produce processing and research center) Govt. Pharmacy Bhopal. And then, *Shadbindu Taila* was prepared in college pharmacy of Pt. Khushilal Sharma Govt. Ayurvedic College, Bhopal with the classical procedure as described in classical text *Chakradatta* (6). The fine powder of *Haridra* (*curcuma longa L.*) dry rhizome was also prepared and slightly roasted with small quantity of cow ghee in college pharmacy.

Criteria for Assessment

Objective Parameters

Absolute eosinophilic count (AEC) and Erythrocytes sedimentation rate (ESR) were assessed as objective parameters.

Subjective parameters

The severity of main symptoms of Allergic Rhinitis (Rhinorrhea, Nasal itching, Nasal obstruction, Sneezing) were assessed on the basis of Total Nasal Symptoms Score (TNSS score) a brief questionnaire developed by Mapi research trust TNSS (2004) (7). The TNSS contain 16 self-rated questions for four symptoms of Allergic Rhinitis i.e. Rhinorrhea, Nasal itching, Nasal obstruction, Sneezing those were assessed with 0-3 grading scale. Score 0 was indicating No symptom, score 1 was indicating mild symptoms (awareness but not troubled), score 2 was indicating moderate symptoms (troublesome but not interfering with normal daily activities or sleep) and score 3 was indicating sever symptoms (interfering with normal daily activities or sleep). The TNSS ranging from 0 (no symptoms) to 12 (maximum symptoms intensity). While, severity of *Vataja Pratishyaya* symptoms such as *Shirashoola*, *Galashosha*, *Nistodashankha*, *Swarbheda* and associated complaints such as *Aruchi*, *Shirogaurava*, *Swaskashta*, *Gandha Hani* were also assessed with 0-3 grading [Table No.1].

Table No.1 Assessment scale of main and associated Symptoms of *Vataja Pratishyaya*

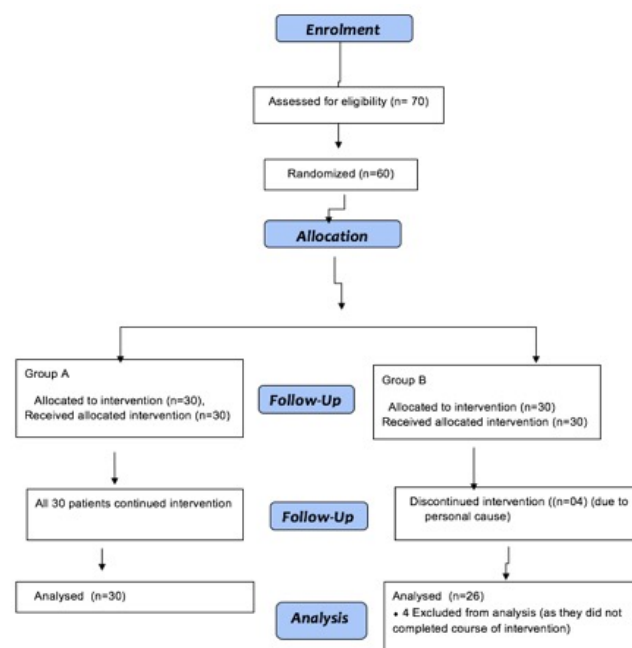
| Symptoms | Severity of Symptoms | Grade |
|---------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------|-------|
| <i>Shirashoola</i> (Headache) | Absent | 0 |
| | Present only during exposure (mild) | 1 |
| | Present only for few hours but not interfering with normal daily activity (moderate) | 2 |
| | Present throughout the day interfering with normal daily activity (severe) | 3 |
| <i>Galashosha</i> (dryness of throat) | Absent | 0 |
| | Present at the time of attack only (mild) | 1 |
| | Present in between attacks (moderate) | 2 |
| | Present throughout the day (severe) | 3 |
| <i>Nistodashankha</i> (Pricking pain in temporal region) | Absent | 0 |
| | Present at the time of attack only (mild) | 1 |
| | Present in between attacks (moderate) | 2 |
| | Present throughout the day (severe) | 3 |
| <i>Swarbheda</i> (Hoarseness of voice) | Absent | 0 |
| | Present at the time of attack only (mild) | 1 |
| | Present only for few hours (moderate) | 2 |
| | Present throughout the day (severe) | 3 |
| <i>Swaskashta</i> (difficulty in breathing) and <i>Shirogaurava</i> (heaviness on the head) | Absent | 0 |
| | Present only during exposure (mild) | 1 |
| | Present only for few hours but not interfering with normal daily activity (moderate) | 2 |
| | Present throughout the day interfering with normal daily activity (severe) | 3 |
| <i>Aruchi</i> (anorexia) and <i>Gandha Hani</i> (loss of smell) | Absent | 0 |
| | Present only during exposure (mild) | 1 |
| | Present only for few hours (moderate) | 2 |
| | Present throughout the day (severe) | 3 |

developed by Graph Pad Software located in San Diego, California was used for statistical analysis.

Observations

Among 60 randomly selected volunteers 56 completed the course of treatment while 04 patients of group 'B' discontinued the study due to personal reason.

Consort Flow Chart:



In present study it was observed that majority 53.33% patients between 21-30 years were suffering from *Vataja Pratishyaya* (Allergic Rhinitis), 65% male and 35% female were found allergic, Maximum 36.67% patients were graduate. Maximum 60% patients were belonging to upper middle class. Maximum 53.33% patients were belonging to urban area. 41.67% patients were reported industrial polluted residence area. 66.65% patients were reported positive family history of Allergic Rhinitis. 55% patients were taking mixed diet. 66.67% were reported consumption of fast food. 40% patients were reported to have *Vishma Agni*, 50% patients were doing *Adhyashana* (frequent consumption of food before digestion of previous food), 26.67% were habitual to take excessive sweet in diet, Maximum 40% patients reported to have irregular bowel habit, 40% patients reported to have urge holding habits for defecation, 63.33% patients were having disturbed sleep due to nasal obstruction, 78.33% were physically inactive, Maximum 48.33% of patients were found to be tea/coffee addicted, 51.67% of patients were reported anxiety, 60% patients were reported to doing sedentary nature of work, majority of the 51.66% patients belonged to *Kapha-Vata Prakruti*.

Presence of Chief complaints

In present study maximum 70% of the patients were found to have chief complaints of Rhinorrea, 50% had nasal itching, 65% had sneezing, 41.67% had nasal obstruction followed by 50% had cough, 88%

Statistical analysis

Manually collected Data was transferred to computer in Microsoft excel sheet. Then, Mean, Mean difference, standard deviation (SD), standard error (SE) were included in analysis, relief in the subjective symptoms were assessed in percentage. Then statistical significance of result was assessed by Wilcoxon matched- pairs signed-ranks test, Mann Whitney test, Paired and unpaired t-test. Graph Pad InStat-3 software

reporting headache, 50% reporting itching in eyes 71.67% itching in nose, 95% patients were reporting recurrent attack of disease.

Associated complaints

70% reported to had *Swash-kashta* (difficulty in breathing), followed by 67% had *Gandhhani* (loss of smell), 70% were reported *Aruchi* (anorexia), 53% patients were reported *Swarabheda* (hoarseness of voice). The presence of these symptoms established that Allergic Rhinitis is similar to *Vataja Pratishyaya*.

Results

In group 'A' the mean of subjective nasal symptoms rhinorrhoea, nasal itching, nasal obstruction, sneezing before treatment was reported 3.133, 2.567, 2.833, 2.967 respectively while after treatment it was

reduced to 0.6923, 0.2308, 0.5000, 0.3462 with ($P<0.0001$) suggested Group A therapy is effective in relieving the symptoms. In group 'B' the mean of subjective nasal symptoms rhinorrhoea, nasal itching, nasal obstruction and sneezing before treatment was 2.733, 2.167, 1.967, 2.167, 8.933 respectively and after treatment it was reduced to 1.433, 1.333, 0.9000, 1.200, 4.867 with ($P<0.0001$) which also indicates the efficacy of the treatment of group B. Inter group comparison reported significant result and more mean difference for subjective symptoms rhinorrhoea, nasal itching, nasal obstruction and sneezing in group 'A' patients 2.308, 2.423, 2.462, 2.615 compare to group B patients 1.300, 0.8333, 1.067, 0.9667 respectively which was indicating that Group A therapy was more effective compare to group B therapy. [Table No.2]

Table No. 2 Effect of Therapy on Chief Complaint (Nasal Symptoms) of Allergic Rhinitis

| Nasal Symptoms | Group | Mean | | MD | % relief | SD | SE | Wilcoxon Matched pairs signed ranks test & p value |
|------------------------------------------|----------|-------|--------|--------|----------|--------|---------|----------------------------------------------------|
| | | BT | AT | | | | | |
| Rhinorrhoea | A (N=30) | 3.13 | 0.6923 | 2.308 | 73.66 | 0.7359 | 0.1443 | W=351.00 N=27 P<0.0001 ES |
| | B (N=26) | 2.733 | 1.433 | 1.300 | 47.56 | 0.6513 | 0.1189 | W=378.00 N=26 P<0.0001 ES |
| Mann-Witney U- statistic 161 p<0.0001 ES | | | | | | | | |
| Nasal itching | A (N=30) | 2.567 | 0.2308 | 2.423 | 94.74 | 1.137 | 0.2231 | W=300.00 N=24 P<0.0001 ES |
| | B (N=26) | 2.167 | 1.333 | 0.8333 | 38.05 | 0.7466 | 0.363 | W=300.00 N=24 P<0.0001 ES |
| Mann-Witney U- statistic 153 p<0.0001 ES | | | | | | | | |
| Nasal Obstruction | A (N=30) | 2.833 | 0.5000 | 2.462 | 86.90 | 1.392 | 0.2730 | W=276.00 N=27 P<0.0001 ES |
| | B (N=26) | 1.967 | 0.9000 | 1.067 | 54.24 | 0.5208 | 0.09509 | W=378.00 N=23 P<0.0001 ES |
| Mann-Witney U- statistic 265 p=0.03 S | | | | | | | | |
| Sneezing | A (N=30) | 2.967 | 0.3462 | 2.615 | 88.15 | 0.6373 | 0.1250 | W=351.00 N=27 P<0.0001 ES |
| | B (N=26) | 2.167 | 1.200 | 0.9667 | 44.16 | 0.6687 | 0.1221 | W=353.0 N=26 P<0.0001 |
| Mann-Witney U- statistic 156 p<0.0001 ES | | | | | | | | |

BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard Error After completion of study the result of the study reported the mean difference for *Shirashoola* (headache), *Galshosha* (Dryness of throat), *Nistodashankha* (pricking pain in temporal region) and *Swarbheda* (Hoarseness of voice) in group 'A' patients were 1.923, 0.769, 0.923, 1.462 respectively with significance ($P<0.0001$) while mean difference in group B were 0.766, 0.500, 1.033, 0.566 respectively with significance ($P<0.0001$). Individually though both groups showed effect on these symptoms. But as mean difference in symptom *Shirashoola*, *Galshosha* and *Swarbheda* reported more in group 'A' therapy compare to group 'B' therapy with significance ($P<0.0001$); group A therapy had been considered more effective compare to group B therapy. Except *Nistodashankh* both groups found to be had similar effect. [Table No.3]

Table No. 3 Effect of Therapy on Vataj Pratishyay Symptoms

| Symptoms | Group | Mean | | MD | % relief | SD | SE | Wilcoxon Matched pairs signed ranks test & p value |
|------------------------|----------|-------|--------|--------|----------|--------|--------|----------------------------------------------------|
| | | BT | AT | | | | | |
| Shirashoola (headache) | A (N=30) | 2.115 | 0.1923 | 1.923 | 90.92 | 0.6884 | 0.1350 | W=325; N=24 P<0.0001 ES |
| | B (N=26) | 2.133 | 1.367 | 0.7667 | 35.94 | 0.5683 | 0.1038 | W=276; N=25 P<0.0001; ES |

| | | | | | | | | |
|-------------------------------------------------------|-------------|--------|--------|--------|-------|--------|---------|-----------------------------|
| Galashosha (dryness of throat) | A (N=30) | 0.8846 | 0.1154 | 0.7692 | 86.95 | 0.5870 | 0.1151 | W=171; N=13 P<0.0001; ES |
| | B (N=26) | 0.8000 | 0.3000 | 0.5000 | 62.5 | 0.6297 | 0.1150 | W=91; N=18 P<0.0001; ES |
| Nistodashank ha (pricking pain in temporal region) | A (N=30) | 1.231 | 0.3077 | 0.9231 | 74.98 | 0.7961 | 0.1561 | W=171; N=29 P<0.0001; ES |
| | B (N=26) | 2.733 | 1.7000 | 1.033 | 37.79 | 0.3198 | 0.05839 | W=435; N=13 P<0.0001; ES |
| Swarbheda (hoarseness of voice) | A (N=30) | 1.700 | 0.3077 | 1.462 | 86.00 | 0.5818 | 0.1141 | W=325; N=13 P<0.0001; ES |
| | B (N=26) | 1.067 | 0.5000 | 0.5667 | 53.11 | 0.7739 | 0.1413 | W=91; N=25 P<0.0001; ES |

BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard Error

After completion of study the result of the study reported the mean difference for *Aruchi* (anorexia), *Shirogaurava* (heaviness on head), *Swas kashtha* (Difficulty in breathing), *Gandhahani* (loss of smell) and *Kasa* (cough) in group 'A' patients were 0.808 (P<0.0001), 1.692 (P<0.0001), 0.308 (P<0.01), 1.856 (P<0.0001) and 2.462 (P<0.0001) respectively while mean difference in group B were 0.400 (P=0.001), 0.667 (P<0.0001), 1.233 (P<0.0001), 1.267 (P<0.0001) and 0.900 (P<0.0001) respectively. Individually though both groups showed effect on these symptoms.

On inter group comparison both group A and group B found equally effective on symptoms *Aruchi* (anorexia) (p=0.9) and *Swas kashtha* (Difficulty in breathing) (p=0.5) while based on percentage relief for symptoms *Shirogaurava* (heaviness on head) (P<0.0001), *Gandhahani* (loss of smell) (p=0.0049) and *Kasa* (cough) (P<0.0001) group A found to be more effective than group B on these symptoms. [Table No.4]

Table No. 4 Effect of Therapy on Associated Complaints

| Associated Complaints | Group | Mean | | MD | % relief | SD | SE | Wilcoxon matched pairs signed ranks test & p value |
|-------------------------------------------|-------------|-------|--------|-------|----------|-------|--------|----------------------------------------------------|
| | | BT | AT | | | | | |
| Aruchi (Anorexia) | A (n=30) | 0.846 | 0.0385 | 0.808 | 95.45 | 0.895 | 0.176 | W=91 N=13 P=0.0002 ES |
| | B (n=26) | 0.433 | 0.0333 | 0.400 | 92.31 | 0.563 | 0.103 | W=611 N=5 P=0.0010 ES |
| Mann-Witney U- statistic 388 p=0.9791 NS | | | | | | | | |
| Shirogaurava (heaviness on head) | A (n=30) | 1.808 | 0.1154 | 1.692 | 93.23 | 0.618 | 0.121 | W=325 N=25 P<0.0001 ES |
| | B (n=26) | 1.900 | 1.233 | 0.667 | 92.32 | 0.547 | 0.099 | W=190 N=19 P<0.0001 ES |
| Mann-Witney U- statistic 93.5 p<0.0001 ES | | | | | | | | |
| Swas kashtha (Difficulty in breathing) | A (n=30) | 0.346 | 0.0385 | 0.308 | 88.87 | 0.549 | 0.108 | W=28 N=20 P=0.0156 S |
| | B (n=26) | 1.433 | 0.2000 | 1.233 | 13.97 | 1.165 | 0.213 | W=210 N=7 P<0.0001 ES |
| Mann-Witney U- statistic 352 p=0.5161 NS | | | | | | | | |
| Gandhahani (loss of smell) | A (n=30) | 2.000 | 0.1538 | 1.856 | 93.92 | 1.084 | 0.213 | W=231 N=29 P<0.0001 ES |
| | B (n=26) | 2.133 | 0.8667 | 1.267 | 59.39 | 0.639 | 0.116 | W=435 N=21 P<0.0001 ES |
| Mann-Witney U- statistic 222 p=0.0049 VS | | | | | | | | |
| Kasa (cough) | A (N=30) | 2.808 | 0.346 | 2.462 | 86.76 | 0.706 | 0.1385 | W=351.00 N=26 P<0.0001 ES |
| | B (N=26) | 2.467 | 1.567 | 0.900 | 57.43 | 0.403 | 0.0735 | W=351.00 N=26 P<0.0001 ES |
| Mann-Witney U- statistic 83 p<0.0001 ES | | | | | | | | |

BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard Error

Mean difference on ESR of Group A was reported 12.038 (p<0.0001) while it was 3.367 (p=0.002) for group B. Result individually both groups were had significant effect on reduction of ESR levels. On inter group comparison group 'A' found to be more effective than group 'B' on ESR as more significant mean difference was reported in group 'A' compare to in group 'B'. Mean difference on AEC of Group A was reported 287.31 (p<0.0001) while it was

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176.67 ($p<0.0001$) for group B. Result individually both groups were had significant effect on reduction of AEC levels. On inter group comparison group 'A' found to be more effective than group 'B' on AEC as more significant mean difference was reported in group 'A' compare to group 'B'. [Table No.5]

Table No.5 Effect of Therapy on Objective Parameters of Allergic Rhinitis

| | Group | Mean | | MD | SD | SE | Paired t test and p value |
|------------------------------------|----------|---------|--------|--------|--------|--------|---------------------------|
| | | BT | AT | | | | |
| ESR (mm)/hrs | A (n=30) | 20.615 | 8.846 | 12.038 | 7.681 | 1.506 | T=7.992 P<0.0001 ES |
| | B (n=26) | 16.9333 | 13.567 | 3.367 | 5.678 | 1.037 | T=3.244 P=0.002 VS |
| Unpaired t test t=2.662 p=0.01 S | | | | | | | |
| AEC cu/mm | A (n=3) | 506.15 | 218.92 | 287.31 | 97.962 | 19.212 | T=14.95 P<0.0001 ES |
| | B (n=26) | 508.33 | 331.67 | 176.67 | 136.59 | 24.938 | T=7.084 P<0.0001 ES |
| Unpaired t test t=3.828p=0.0003 ES | | | | | | | |

BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard Error

Mean difference on frequency of recurrent attacks of Allergic Rhinitis of Group A was reported 2.115 ($p<0.0001$) while it was 0.900 ($p<0.0001$) for group B. Result individually both groups were had significant effect on reduction of recurrent attacks of Allergic Rhinitis. On inter group comparison group 'A' found to be more effective than group 'B' on frequency of recurrent attacks based on results of more significant mean difference and relief in percentage 76.89% in group 'A' compare to 52.47% in group 'B'. [Table No.6]

Table No.6 Effect of Therapy on Recurrent Attacks of Allergic Rhinitis

| | Group | Mean | | MD | % relief | SD | SE | Wilcoxon matched pair signed ranks test & |
|------------------------------------------|----------|-------|-------|-------|----------|-------|--------|-------------------------------------------|
| | | BT | AT | | | | | |
| Recurrent Attacks of Allergic Rhinitis | A (n=30) | 3.115 | 1.000 | 2.115 | 76.89 | 0.952 | 0.1867 | W=325 N=30 P<0.0001 ES |
| | B (n=26) | 3.367 | 1.667 | 0.900 | 52.47 | 0.679 | 0.1240 | W=465 N=25 P<0.0001 ES |
| Mann-Witney U- statistic 221 p=0.0055 VS | | | | | | | | |

BT: Before treatment, AT: After treatment, MD: Mean difference, SD: Standard deviation, SE: Standard Error

Overall effect of therapy was assessed by TNSS score between 0 to 12 score. In group A, before study 40% and 60% patients were reported between moderate to severe scale of TNSS while after study 66.67%, 26.67% and 6.66% were reported between mild, moderate and severe scale of TNSS. While, in Group B, before study 38.46% and 61.54% patients were reported between moderate to severe scale of TNSS while after study only 11.54% patients were reported under mild symptoms scale and 50% and 38.46 % were reported between moderate and severe scale of TNSS. Hence, result of overall effect of study based on total nasal symptoms score revealed that group A therapy was more effective compare to group B in the management of Allergic Rhinitis. [Table No.7]

Table No.7 Overall Effect of Therapy on TNSS Score of Group A & B

| TNSS Score | No. of patients | | | |
|----------------|-----------------|-------------|---------------|-------------|
| | Group A(n=30) | | Group B(n=26) | |
| | Before | After | Before | After |
| 0 (No symptom) | 0 (0%) | 0(0%) | 0(0%) | 0(0%) |
| 1-4 (Mild) | 0 (0%) | 20 (66.67%) | 0 (0%) | 3 (11.54%) |
| 5-8 (Moderate) | 12 (40%) | 8 (26.67%) | 10 (38.46%) | 13 (50%) |
| 9-12 (Sever) | 18 (60%) | 2 (6.66%) | 16(61.54%) | 10 (38.46%) |

Discussion

In present study relief on chief complaints Rhinorrhoea, Nasal Itching, Nasal Obstruction and Sneezing were reported 73.66%, 94.74%, 86.90%, 88.15% respectively with $p<0.0001$ in group 'A'

patients. While, relief observed in group 'B' patients were 47.56%, 38.05%, 54.24%, 44.16%, respectively ($p<0.0001$). Additionally, more relief on associated symptoms such as Difficulty in breathing, loss of smell and cough were reported in group 'A' patients 88.87%

($p < 0.01$), 93.92% ($p < 0.0001$) and 86.76% ($p < 0.0001$) respectively while, in group 'B' relief were reported 13.97 %, 59.39% and 57.43% with significance ($p < 0.0001$). Based on objective criteria, group 'A' found to be more effective than group 'B' as for ESR more significant mean difference 12.038 ($p < 0.0001$) was reported in group 'A' compare to 3.367 ($p = 0.002$) in group 'B' and for AEC more significant mean difference 287.31 ($p < 0.0001$) was reported in group 'A' compare to 176.67 ($p < 0.0001$) in group 'B'. Percentage relief on recurrent attacks of Allergic Rhinitis in Group A patients was reported 76.89% ($p < 0.0001$) while it was only reported 52.47% ($p < 0.0001$) for group B patients. TNNS score also revealed maximum relief reported in group 'A' patients as after therapy 66.67% (20 patients) were brought down to mild symptom score followed with 26.67% ($n = 8$) moderate and only 6.66% ($n = 2$) were reported sever symptom score compare to group 'B' patients were reported 11.54% ($n = 3$) mild, 50% ($n = 13$) moderate and 38.46% ($n = 10$) sever score. This observation indicating that combined therapy *Shadbindu Taila Pratimarsha Nasya* along with oral administration of *Ghrit Bhrisht Haridra* (*curcuma longa* L. powder roasted with cow-ghee) were provided better relief in all subjective and objective parameter in comparison to oral administration of *Ghrit Bhrisht Haridra* alone in the management of *Vataja Pratishyaya* (Allergic Rhinitis).

Probable Mode of Action of *Shadbinu Taila Pratimarsha Nasya* Therapy

Nose is identified as most suitable route for drug delivery for allergic and non-allergic rhinitis as because of the rapid absorption of drug due to avoidance of first-pass metabolism and large nasal mucosa surface area (8). But, a drug should be select carefully which should not interfere with normal nasal function, especially mucociliary clearance function which is first line of defence of the ciliated epithelium of the respiratory tract against inhaled particles. The cilia of ciliated epithelium are help to move pathogens and inhaled particles trapped in the mucous layer out of the airways. Inhibition of the mucociliary clearance system induces a longer contact time of nasal mucosa with captured particles and irritants, which lead to airway infection (9). Pandya VK, Tiwari RS reported in allergic rhinitis nasal mucociliary clearance was significantly prolonged compare to healthy adults (10).

Pratimarsha Nasya (administration of oil based nasal drops) in Ayurveda used to prevent and to treat *Urdhvajatrugata ragas* (diseases develop above the clavicle region of body) (11) it have potential to prevent the damage of mucociliary clearance system and strengthen the system. Administration of oil based nasal drops (*Pratimarsha Nasya*) work as barrier in nasal cavity by creating protective sheath over mucosal membrane of nose thus prevent the entry of allergens in the body and provide protection action against pollutants like dust, smoke pollen grains excetra (12). Thus, beneficial for individual who continuously travels in highly polluted area and having symptoms like sneezing, rhinorrhoea, and blockage of nose.

Aggravated *Vata dosha* is considered as main factor which develops *Vataj Pratishyay*. Hence, reduction in *Vata Dosha* needed to treat such diseases. Present study used *Shadbindu oil* for *Pratimarsha Nasya* which contains root of *Eranda* (*Ricinus communis* L.), *Rasna* (*Pluchea lanceolate* DC.), *Tagar* (*Valeriana wallichii* DC.), *Shatavha* (*Aanethum graveolens* L.), *Jeevanti* (*Laptadenia reticulate* Retz.), *Vidanga* (*Embelia ribs* Burm. f), *Bhrangraj* (*Eclipta alba* L.), *Yashtimadhu* (*Glycyrrhiza glabra* L.), dry ginger, rock salt, Sesame oil, goat milk etc. drugs (13) those are having *Kaph* and *Vata Dosha* pacifying properties thus might be helpful in the reduction of inflammatory process of upper respiratory tract started due to allergens and due to oil base was able to prevent the absorption of allergens and also was able to maintain proper mucociliary clearance therefore was able to reduced congestion and oedema of nasal cavity and strengthen and the respiratory system. Furthermore, *Shadbindu taila* also by nourishing and strengthen the mucosa membrane might be able to, reduced Neurogenic inflammation occur due to destroyed respiratory epithelium and exposed nerve endings, and thus was able to reduced Non-specific hyper responsiveness. Hence was able to reduce sneezing and itching of nasal passage. Thus, in present study *Pratimarsha Nasya* therapy has sown extremely significant effect in treatment of allergic rhinitis by reducing sneezing, rhinorrhoea itching, nasal obstruction and oedema in nasal passage. Another study conducted by Shiva Kumar et.al (2014) with *Anutaila Pratimarsha Nasya* also reported marked improvement in symptoms with ($p < 0.001$) and in TNSS, TLC and AEC also with ($p < 0.001$) (14).

Probable Mode of action of *Ghrutabristha Haridra* (*curcuma longa*) Powder

Allergic diseases and symptoms occur because of an reaction of active immune system to allergens due to IgE antibodies which releases of histamine, a chemical that can cause rashes, runny nose, sneezing and itching (15). *Haridra* (*Curcuma longa* L.) is known for its multiple health restoring properties, and has been used in treating several diseases including respiratory disorders due to its anti-allergic properties with inhibitory effect on histamine release from mast cells (16). This anti-histamine property helps in controlling the allergic symptoms as Allergy and Asthma are pro-inflammatory diseases, developed due to inflammatory cytokines (Shehzad et al., 2013) (17).

Main contain of *Haridra* is curcumin, which belongs to hydroxyl groups and had been indicated to decrease the allergic reactions due to its anti-inflammatory effect in several research studies. Another study, reported that the curcumin greatly affected both the innate and adaptive immunity through modulating immune cells function including neutrophils, macrophages, monocytes, natural killer cells, dendritic cells, T cells, and B cells (18). Curcumin alleviated nasal symptoms (sneezing and rhinorrhoea) and nasal congestion through reduction of nasal airflow resistance (19) Thus, use of *Haridra* in present study had been

alleviated nasal symptoms (sneezing and rhinorrhoea) and nasal congestion through reduction of nasal airflow resistance. Ayurveda also considered that it had anti-inflammatory (*Shothahara*) and Anti-allergic properties because of its *ushna virya* with *katu vipaka*, *laghu* and *ruksha* properties (20) it was able to pacifying *kapha vata dosha* and due to its sharp properties it was able to penetration of the drug into *sukshma srotas* and thereby able to clear nasal obstructions and dry property had been able to reduce rhinorrhoea. Also, due to its *shothahara* (anti-inflammatory) properties, it was able to reduce swelling of nasal mucosa and due to its *vranaropana* (wound healing) (21) properties it might be working as good healer and reduces inflammation of nasal mucosa as well as was able to reduce Neurogenic inflammation.

Conclusion

In Allergic Rhinitis patients due to continuous exposure of allergens Neurogenic inflammation occurs due to destroyed respiratory epithelium and exposed nerve endings. So, nerve fibres get excited by nonspecific stimuli. Thus, non-specific hyper responsiveness occurs. In present study significant relief in all subjective and objective parameter of *Vataj Pratishyay* (Allergic rhinitis) were reported in combined therapy i.e. *Shadbindu Taila Pratimarsha Nasya* along with oral administration of *Ghrit Bhrisht Haridra* (*curcuma longa* powder roasted with cow-ghee) group. This might be due to anti-inflammatory property of *Shadbindu Taila Pratimarsha Nasya* and *Ghrit Bhrisht Haridra* (*curcuma longa* powder roasted with cow-ghee) and wound healing property of *Haridra* (*curcuma longa*).

Limitation

The present study was conducted in limited time, on limited number of subjects and specific parameters of allergy such as IgE and skin prick test were not assessed in this study.

Further Recommendation

Further study with larger number of participants with long duration minimum 3 months by taking specific biological parameters such as IgE can be planned.

Conflict of Interest – Nil

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