Management of Allergic Rhinitis through Ayurvedic Formulation: A Single Arm Clinical Study

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Research

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Abstract

**Background:** Allergic rhinitis is one of the most common and most prevalent ailments, familiar to all with an equal distribution more or less throughout the world, rather without any exception to the developed and under developed countries. Repeated attack and improper management of the disease leads to many complications like recurrent sinusitis, nasal polyps, serous otitis media, orthodontic problems etc.

**Objective:** To evaluate the role of Ayurvedic Formulations in the management of Allergic rhinitis

**Materials and methods:** The study was executed as on open label, multicentric, prospective clinical study executed at (CARI, New Delhi and CARI, Mumbai). Sixty participants aged between 18 and 65 years, having the symptoms of Allergic rhinitis were enrolled in the study as per the inclusion and exclusion criteria. The intervention given to the participants were Ayush VPR (3.5gm) in the form of *Churna* (powder) twice a day with honey and *Ghrita* (clarified butter) after food, *Shirishadi Kwath* (20 ml) twice a day, orally in empty stomach and *Nasya* (intranasal drug administration) with *Anutaila* for 07 days for two consecutive cycles with the interval of seven days. The assessment was done every week. Total duration of intervention was 28 days followed by follow up of 28 days on the interval of 14 days. The primary outcome was assessed by seeing the change in the CARAT (Control of Allergic Rhinitis and Asthma Test) score with Mauchly's test of sphericity (b).

**Results:** The mean CARAT score was found to reduce subsequently from baseline to 7th, 14th, 21st and 28th day. A significant improvement in the mean total CARAT score ($p < 0.001$) was observed after 28th day of treatment and also at the end of the 56th day in comparison to baseline (Mauchly's Test of Sphericity (b) Measure)

**Conclusion:** The Ayurvedic formulations, *Shirishadi Kwath*, Ayush VPR and *Anutaila* are safe and significantly reduced rhinorrhea, nasal itching, Sneezing fits, nasal congestion, and nasal obstruction. The present study reveals that Ayurvedic treatment according to the line of treatment of *Vataja Pratishyaya* provided highly significant relief from Allergic rhinitis.

**Key Messages Regarding Feasibility**

- **What uncertainties existed regarding the feasibility?**

  The procedure *Nasya* (Nasal instillation of medicine) was carried out for 7 days in every patient. It was quiet difficult or less feasible for patient to come hospital daily for 7 days.

- **What are the key feasibility findings?**

  This study was conducted at Delhi and Mumbai which are the polluted cities of India and nasal allergy is reported in large number of cases in Delhi and in Mumbai. So it was very easy to get patients of Allergic rhinitis from these cities.
What are the implications of the feasibility findings for the design of the main study?

The feasibility design is considered to have low methodological quality compared with an RCT, the gold standard of study designs. Limitations of this study are therefore lack of a control group and no blinding. Further, the small sample size made it difficult to make solid conclusions on the effect of Ayurvedic treatment; however, based on current and previous results, Ayurvedic treatment is anticipated to be safe.

Introduction

Allergic rhinitis (AR) is a symptomatic disorder of the upper respiratory tract which is induced after exposure to allergens via Ig E mediated hypersensitivity reactions, characterized by 4 cardinal symptoms viz watery rhinorrhea, nasal obstruction/nasal congestion, nasal itching and sneezing. This study was conducted at Delhi and Mumbai which are the polluted cities of India and nasal allergy is reported in large number of cases in Delhi and in Mumbai also. The burden of AR constitutes about 55% of all allergies. About 20–30% of Indian population suffers from at least one allergic disease. Reported incidence of allergic rhinitis in India also ranges between 20–30%, studies have shown that prevalence of allergic rhinitis has been increasing in India over past few years. Based on similarities in etiological factors and clinical features, Allergic Rhinitis may be correlated with Vataja Pratishyaya in the context of Ayurveda. In modern medical system, a wide range of antibiotics and decongestants are available. But these drugs give only symptomatic relief and also are not devoid of adverse effects. Previously many research works have been carried out for the alleviation of Allergic Rhinitis with Ayurvedic medication but there is no definite treatment protocol designed and followed. By keeping this fact in mind, the following treatment protocol has been proposed as suggested on Doshik basis by Late Vaidya Shriram Sharma of Mumbai, former president, Central Council of Indian Medicine (CCIM), New Delhi. This treatment protocol has been followed successfully by many Ayurveda physicians with promising results. The treatment protocol includes Ayush VPR (Table 1), Shirishadi Kwath (an Anubhoota Yoga) (Table 2), and Nasya (intranasal drug administration) with Anutaila. The present study was undertaken with an objective to assess the efficacy of Ayurvedic formulations, Ayush VPR, Shirishadi Kwath and Nasya with Anutaila in the management of Allergic rhinitis.

Materials And Methods

Eligibility criteria for participants:

Inclusion Criteria

Participants of either gender aged between 18 to 65 years with clinically diagnosed as patients of Allergic rhinitis/ persisting symptoms of Allergic rhinitis, diagnosis was confirmed by the supportive investigations such as X-ray (PNS), Nasal endoscopy and other laboratory investigations suggestive diagnosis of AR. Participants who were able & willing to participate and provided signed informed consent were included in the study.
Exclusion Criteria

The participants having the following criteria were not enrolled in this study; history of chronic nasal or upper respiratory tract symptoms or disorders other than allergic rhinitis, history of non-allergic rhinitis, chronic sinusitis or serve asthma, participants with nasal anatomical defects (severe deviated nasal septum), participants with acute episodes i.e., fever/earache/headache, participants with associated tonsillitis or airway obstructions (adenoids), has a nasal condition likely to affect the outcome of the study. Participants taking any treatment of H1 antihistamine medication, non-steroidal analgesics, corticosteroids nasal drops, leukotriene antagonists, nasal vasoconstrictors. Pregnant ladies and Lactating mothers, participants suffering from any debilitating chronic disease like tuberculosis, Uncontrolled Diabetes mellitus, any unstable cardio-vascular diseases, participants with evidence of malignancy, participants with concurrent hepatic disorder (defined as Aspartate Amino Transferase (AST) and / or Alanine Amino Transferase (ALT) > 2 times upper normal limit or Renal Disorders (defined as S. creatinine > upper limit of Lab. value), Pulmonary Dysfunction (Bronchial Asthma and / or Chronic Obstructive Pulmonary Disease [COPD]), participants with mental disorder, and those who are currently participating in any other clinical trial were excluded from the clinical trial.

Study setting: This study was carried out at two clinical units of the Central Council for Research in Ayurvedic Sciences viz Central Ayurveda Research Institute (CARI), New Delhi and Central Ayurveda Research Institute (CARI), Mumbai. Before the commencement of the study, ethical clearance was obtained separately by each institute from the Institutional Ethical Committee. The study was conducted according to CCRAS research policy considering the ICH-GCP guidelines and Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research on human participants, adopted from World Medical Association (WMA) Declaration of Helsinki. The trial had been registered in the clinical trial registry of India (CTRI/2017/12/010937 [Registered on: 21/12/2017]).

Interventions:

- A coded formulation (Ayush VPR) was used in powder form (Chuma) in the dose of 3.5 gms orally with Honey and Ghee (clarified butter) twice a day after food for 04 weeks.
- Shirishadi Kwath—20 ml, twice a day was given orally in empty stomach for 04 weeks.
- Local Snehana (oil massage) and Nadi swedana (medicated fomentation) as a Purvakarma followed by Anutaila— intranasal drug administration (Nasya-6 drops in each nostril) and Swedana, Kavala (gargles) with lukewarm water was done as paschatkarma. This procedure was carried out for 07 days for two consecutive cycles with the interval of 07 days.

Procurement of Drugs

Ayush VPR (Table-1) and Anutaila procured from the Pharmacy of Institute of Post Graduate Teaching & Research in Ayurveda, Gujarat Ayurveda University, Jamnagar and Shirishadi Kwath (Table-2) was procured from CARI, Patiala. Quality control and standardization of finished products were also carried
Both the drugs were procured from GMP certified pharmacy, following the standards of Ayurvedic Pharmacopeia of India.

**Primary Outcome Measures**

To evaluate the effect of Ayurvedic Formulations in the management of Allergic Rhinitis, in terms of CARAT score.

**Sample Size**

60 (30 in each centre)

**Statistical methods**

The data was collected at baseline, 7th day, 14th day, 21st day, after the treatment and follow up visit, tabulated and analyzed by using appropriate statistical methods. Clinical symptoms, subjective parameters, and laboratory parameters were subjected to univariate and multivariate analysis using statistical package for social sciences (SPSS), 15.0 versions, with appropriate statistical methods.

**Study Procedures**

Participant approaching the outpatient department and having cold due to allergy from dust, fume etc. were screened for the study. The participants were explained adequately about the study by providing the participant information sheet and the informed consent form in the regional language to make decision about their participation in this study. The voluntary written consent was obtained from each participant, and the participants were informed that all trial results recorded will be treated in strict confidence. After clinical assessment, the participants were sent for laboratory investigations, X-ray (PNS) and Diagnostic nasal endoscopy. The participants were screened based on inclusion and exclusion criteria after signing written informed consent. The enrolled participants were assessed in the baseline evaluation based on their socio-demographic data, symptoms, medical history, drug history, Ayurveda assessment criteria, CARAT scoring in the CRF and e-format thereafter, the participants were enrolled in trial. The CARAT Score containing 10 questions (Q) was used to grade Allergic rhinitis (Sum of all 10 questions, 0-worst, best – 30). Ayurveda formulation as trial medicine were given for the period of 7 days and the subjects were advised to return empty containers of trial medicines on every follow-up visit in order to check the drug compliance.

**Assessment and Follow up**

The participants were assessed every week up to one month (i.e., 7th, 14th, 21st and 28th day) to ensure the drug compliance, to give them study medication for the next week and to record any adverse effect. The follow-up was done on every 14th day for 04 weeks.

**Laboratory Investigations**
Laboratory parameters, such as liver function tests (LFT), renal function tests (RFT), complete blood count (CBC), erythrocyte sedimentation rate (ESR), hemoglobin (Hb)%, AEC (Absolute Eosinophil count), Fasting blood sugar and X-ray (PNS) were done at baseline. All the laboratory investigations were done at the end of the 28th day also.

**Results**

**Demographic Profile of Study Participants**

The study was conducted on 60 participants (30 in each center). Out of these, 51 participants completed the study, 09 dropped out; the imputation technique was applied on 9 cases. (Fig. 2) The data of four participants were taken for analysis along with the data of the completed cases by the last observation carried forward method for intention-to-analysis. Data of participants were used for analysis. The mean age was found 35.8 ± 12.12. It was found that females (51.7%) were slightly more sufferers than males (48.3%). 95% participants were literates among the total number of participants. Maximum numbers of participants were desk workers (48.3%) while, 30% participants were house wives. Among the total participants, 96.7% were above the poverty line. The majority of the participants (88.1%) were lives in urban, 95% were Hindus and 55.0% were vegetarians. It was found that 78.3% of the participants had normal sleep and 70% had regular bowel habit. History of allergy to dust was found in 96.7% participants whereas allergy to pollens was found in 1.7% participants. It was observed that the maximum numbers of participants were of Pitta-Kaphaja Prakriti (63.3%) followed by Vata-Pittaja Prakriti (33.3%) (Table 3).

**Effect of the Drugs on Outcome Measures on the CARAT Score**

The mean CARAT score was found to reduce subsequently from baseline to 7th, 14th, 21st and 28th day (Fig. 1). A significant improvement in the mean total CARAT score (p < 0.001) was observed after 28th day of treatment and also at the end of the 56th day in comparison to baseline (Mauchly's Test of Sphericity(b) Measure)(Table 4).

**Effect of the drugs on chief complaints of the study participants**

Significant improvement in cardinal features of Allergic rhinitis, i.e., rhinorrhea (excess nasal secretion), nasal itching, sneezing fits, nasal congestion and nasal obstruction was observed at the end of therapy (28th day) and follow-up (56th day) in comparison to baseline (Cochran's Q test) (Table 5).

**Effect of the drugs on laboratory parameters**

It is observed that laboratory parameters, such as the total leukocyte count (TLC), differential leukocyte count (DLC), erythrocyte sedimentation rate (ESR), LFT and RFT were not changed significantly from baseline to the end of the treatment (Table 6).
Discussion

Data obtained in the study reveals that, maximum numbers of the participants were young adults. This is in accordance with the fact that prevalence of AR does not follow the restriction of the age, but is comparatively more common in middle aged persons owing to an excessive involvement in outdoor activities (for making their career and/or earning livelihood) and thus getting an increased exposure to the aggravating factors like dust, fumes, cold wind etc. All participants i.e., 100% were having complaints of rhinorrhea (excess nasal secretion), followed by 91.7% participants who had nasal itching. Sneezing fits was observed as chief complaint in 96.7% of participants whereas 80% participants were having complaint of nasal congestion and nasal obstruction. Data represented that, all symptoms mentioned in classics and in modern science were present in most of the participants. All these symptoms are due to immunologic processes in both nasal and bronchial tissue involve TH 2 lymphocytes and eosinophils. Eosinophils release an array of proinflammatory mediators, including cysteinyl leukotrienes, cationic proteins, eosinophil peroxidase, and major basic protein, and might serve as a major source of IL-3, IL-5, GM-CSF, and IL-13. Neuropeptides also appear to contribute to the pathophysiology of AR symptoms. Sneezing and rhinorrhoea are most common complaint of Allergic rhinitis and are synonymous with it. According to Ayurveda all these symptoms are described due to Vata & Kapha. Kshavathu is due to vitiated Vata in root of nose. Nasanaha/ Nasapratinaha (Nasal blockage) is due to Kaphavruta Udana Vata. In Nasa Srava, there is clear mention of Kapha Dushti by Acharya Dalhana. There are two main classes of participants suffering from Allergic rhinitis, sneezers & runners and blockers. Generally, nasal blockage is experienced in late phase of allergic reactions but in case of repeated exposures early and late phases may overlap each other.

The specific etiology for Vataja Partisyaya has not been delineated in Ayurveda classical texts. However, the etiology and treatment modalities described in the context of vata prakopaka hetu and vata-kaphaja chikitsa can be mentioned here.

Ashwagandha (Withania somnifera) have immune modulatory and anti-inflammatory effect and also pacify Vata, give nourishment to Dhatu. Ashwagandha will reduce inflammation of nasal mucosa and allergic reaction. Sameera Pannaga Rasa is well known effect on Tamaka Shwasa. Sameera Pannaga Rasa is a safe and proven drug for Tamaka Shwasa, one factor responsible in its etiology is allergy.

Shirisha (Albizzia lebbeck (L)Benth.) is Visha Shamaka drug mentioned by all ancient texts. Allergic condition can be correlated with Dushivisha in Ayurveda. Dushivisha remains in body and shows its effects on getting exposed to etiological factors; same is true with allergic reactions. Thus, it can be said that Shirisha will help in reducing symptoms as well as recurrence of AR. Shirisha is found to have potent anti-allergic and mast cell stabilizing activity. Vasa (Adhatoda vasica Nees), Pushkarmoola (Innula racemosa Hk. f.) and Haridra (Curcuma longa L.) also have proven anti-allergic effect.

In the study, Nasya is the chief Shodhana procedure selected because it is the one and only procedure which can perform Uttamanga (Supra clavicular region) Shuddhi. As the name indicates Anutaila has virtue of entering in minute channels. Due to its Sukshma Guna, Anutaila possess a good spreading
capacity through minute channels. Mention of Anutaila in Swasthavrutiya Chatushpada signifies Prakruti Sthapana property of it, which means that drug, can be used in diseased condition to pacify Dosha, as well as in healthy condition to prevent recurrence.

In the present study, highly significant improvement was found in rhinorrhea, nasal itching, Sneezing fits, nasal congestion and nasal obstruction. The improvement remained steady at the end of the follow-up without treatment. This shows the long-term effect of the treatment. The Ayurvedic formulations had no adverse consequences on liver and kidney functions during the study as evident from safety parameters. The drug was well tolerated by the majority of the participants.

Conclusion

The Ayurvedic formulations, Shirishadi Kwath, Coded formulation (Ayush VPR), and Anutaila, are safe and significantly reduce rhinorrhea, nasal itching, Sneezing fits, nasal congestion, nasal obstruction. The present study reveals that Ayurvedic treatment according to the line of treatment of Vataja Pratishyaya provided highly significant relief from Allergic rhinitis. The improvement remained steady even after four weeks of the completion of treatment. This shows the efficacy and long-term benefits of the treatment.

Ethics and consent to participation

This research protocol had been reviewed and approved by the institutional Ethics Committee of Central Ayurveda Research Institute, New Delhi. The trial was conducted in accordance with ethical principles that have their origin in the Declaration of Helsinki for biomedical research and ICMR ethical guidelines involving human participants (2006), and that are consistent with Indian / ICH Good Clinical Practice (GCP) guidelines and written informed consent for participation and publication was taken prior to enrollment in study trial.

Declarations

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Competing interests: None

Author's Contribution: Conceived and designed the trial: SM, NB, BY, BCSR, NS, KSD. Acquisition of data: SM, PD, NB, KP, LB. Analyzed the data: RS. Manuscript drafting: SM. Revised the manuscript critically:
SM, BY. Accountable for all aspects of the work in ensuring those questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: SM, PD, NB, KP, LB, BY, BCSR, B, NS, KSD.

**Availability of data and material:** The datasets generated and/or analyzed during the current study are available from the corresponding author upon reasonable request

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**References**


Tables

Tables 1 to 6 are available in the Supplementary Files section

Figures
Figure 1

Effect of therapy on the CARAT score
Figure 2
Flow diagram of Study Participants

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table.pdf
- CONSORT2010ChecklistMSWord.doc