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Research Article

CLINICAL INVESTIGATIONS ON THE AYURVEDIC MANAGEMENT OF ALLERGIC RHINITIS *(VATAJA PRATISHYAYA)* BY *PRATIMARSHA NASYAAS* NASAL DRUG DELIVERY SYSTEM.

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ABSTRACT: Allergic Rhinitis (AR) is an immunoglobulin (Ig) E mediated inflammatory disease caused by the inflammation of airway mucosa with hypersensitivity resulting from seasonal or perennial responses to specific allergens. Prevalence of AR is increasing and has risen considerably in the past few decades with self reported prevalence up to 41%. According to *Ayurvedic* texts indication of *Anutaila* (classical Ayurvedic oil preparation) used in the form of *Pratimarsha Nasya* a traditional nasal drug delivery system has been used for a long period has shown beneficial effects on diseases of head and neck. A pretest and post test design of single group consisting of 37 patientsdiagnosed as allergic rhinitis were administered *Pratimarsha Nasya* (PN)with *Anutaila* daily for a period of 60 days. Effect of*Pratimarsha Nasya* with *Anutaila* on the chief complaints and totals nasal symptom score showed ameliorative improvement with statistical significance. Laboratory immunological parameters which included Total Leucocyte Count, Absolute Eosinophil Count, Neutrophils and Lymphocytes showed improvement with high statistical significance (< 0.001). At the end after 60 days of medication the patients showed marked relief in symptoms which can open a new direction in Ayurveda inspired novel targeted drug delivery systems.

Key words: Nasal drug delivery system, Allergic rhinitis, Ayurveda, Rhinorrhoea, Anutaila, Ayurveda inspired drug discovery.

INTRODUCTION

Allergic Rhinitis (AR) is an immunoglobulin (Ig) E mediated inflammatory disease caused by the inflammation of airway mucosa with hypersensitivity resulting from seasonal or perennial responses to specific allergens, characterized by sneezing, rhinorrhoea, congestion and obstruction of the nasal passages;conjunctivalor pharyngeal itching and lacrimation (Schapowal 2002; Jung *et al*., 2012; Mygind 1993; Bousquet *et al*., 2001; Passalacqua and Durham 2007).AR also

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triggers systemic inflammation and is associated with various co-morbid conditions such as asthma, nasal polyposis, rhino-sinusitis, serous otitis media and sleep disorders (Liam *et al*., 2002;Shinmei *et al*., 2009; Davies *et al*., 2012; Jung *et al*., 2012). Prevalence of AR is increasing and has risen considerably in the past few decades with self reported prevalence up to 41%. In south-east Asia there are only few published studies of allergic rhinitis among adults (Lam *et al*., 2011; Adelroth *et al*., 2000). Epidemiological datashows prevalence of AR differs between countries and areas within countries (Papadopoulos *et al*., 2012; Asher *et al*., 2006). Allergic sensitization to airborne allergens causes AR while urban living and exposure to air pollution at home and at work place are the common risk factors (Schapowal 2002; Lam *et al*., 2011;Rönmark and Perzanowski, 2003). Allergic rhinitis is not a cause of mortality, but it poses a significant ongoing health burden in the society having major impact on the quality of life, daily functioning (Seth *et al*., 2007). Current clinical management primarily relies on allergen avoidance, treating symptoms as they arise (often using medications such as b2 agonist inhalers, antihistamines and adrenaline) and generalized suppression of immune responses (e.g. using corticosteroids) (Mackenzie *et al.,* 2011)

Ayurveda describes *Pratishyaya* as one of the most important diseases among *Nasaroga* (diseases related to nose) defined as the condition where the secretion produced due to the derangement of *Vata and Kapha* (*i.e.* bodily humours) at the root of the nose, which flows down through the nose against the inspired air (Sharma and Dash 2001).Among different types of *Pratishyaya* the most commonly occurring is *Vataja Pratishyaya*. The disease *Vataja Pratishyaya* is old as existence of human beings. *Vataja Pratishyaya* and its clinical manifestations in the Ayurvedic Classics are very much comparable to the disease Allergic Rhinitis (Shastri 2003).

Ayurveda is the system of medicine, which proposes the need of undertaking the purification of biological system from gross channels up to molecular levels aiming to clear the entire body of vitiated factors, which render prevention of disease & promotion of health. The treatment of this disease should be bidirectional as indicated by its *Vata and Kapha* (*i.e.* bodily humours) predominance, for that *Shodhana* (purificatory) therapies should be given due importance. *Nasya*(nasal insufflations) is one such purificatory procedure in order to prevent, control and cure, the *Urdhvajatrugata rogas*(diseases of head and neck) as*nasa* (nose) is the door to *shiras*(head) (Bhakti *et al.,* 2009). Medication administered through nose to get desired therapeutic effectis known as *nasya* therapy, which includes medicated oils and powders acting on nasal mucosa (Martens *et al.,* 2011). *Nasya* is an important procedure explained under *Vaiyaktika Swasthavritta* (*i.e.* preventive medicine and personal hygiene) as one of the cleaning process for channels in head and neck region. *Nasya* can be advised in a person for treatment as well as prevention of diseases. Different types of *nasya* procedures are mentioned on the basis of its action, and doses of medicine in the Ayurvedic classics. Among them *Pratimarsha nasya* has significant role in the prevention of *Urdhvajatrugata rogas* and promotion of health of sense organs. *Pratimarsha nasya* is given importanceas a daily regimen in *Swastha* (healthy) persons and are advised to practice it

Table 1. Ayurvedic severity of symptoms assessment scale.

Symptoms	Severity of Symptoms	Grade
Kshavathu (Sneezing)	Absent	0
	Present only during exposure	1
	Present only in the morning and evening	2
	Present throughout the day	3
Tanusrava (Running nose)	Absent	0
	Present only during exposure	1
	Present only in the morning and evening	2
	Present throughout the day	3
Aanadhwa (Nasal blockage)	Absent	0
	Present only during exposure	1
	Present only in the morning and evening	2
	Present throughout the day	3
Shirashoola (Headache)	Absent	0
	Present only during exposure	1
	Present only for few hours	2
	Present throughout the day	3
Galashosha (dryness of throat)	Absent	0
	Present at the time of attack only	1
	Present in between attacks	2
	Present throughout the day	3
Nistodashanka (Pricking pain in temporal region)	Absent	0
	Present at the time of attack only	1
	Present in between attack	2
	Present throughout the day	3
Swarabheda (Hoarseness of voice)	Absent	0
	Present at the time of attack only	1
	Present for few hours	2
	Present throughout the day	3

Table 2. Assessment scale based on severity of symptoms and total nasal symptom score (TNSS).

Total nasal symptom score (TNSS)		
Symptom	**Domain**	**Scale**
Rhinorrhoea	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3
Nasal itching	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3
Nasal obstruction	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3
Sneezing	no symptom	0
	mild – awareness but not troubled	1
	moderate – troublesome but not interfering with normal daily activities or sleep	2
	severe – interfering with normal daily activities or sleep	3

inorder to get protection from *Urdhvajatrugata rogas.* Apart from this *Pratimarsha nasya* helps to improve oral hygiene, strengthens dentures and improves visual perception etc. According to *Ayurvedic* textsindication of *Anutaila* used in the form of *Pratimarsha nasya* for a long period has beneficial effects on diseases of head and neck.Concept *ofAnutaila* tells that it reaches to minute channels of the body with administered dose ofonly two drops in each nostril (Modha *et al.*, 2009).

MATERIALS AND METHODS

The study was conducted by Ayurvedic

Table 3. Changes in Allergic Rhinitis (AR) Clinical Status on Ayurvedic symptoms after 60 days of treatment by *PratimarshaNasya*with *Anutaila* (n=37).

Descriptive statistics – Ayurvedic assessment of symptoms														
	Kshavathu		Tanusrava		Aanadhwa		Shirashoola		Galashosha		Nistodashanka		Swarabheda	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Mean	2.89	0.92	2.84	0.73	2.59	0.78	1.49	0.51	1.78	0.78	1.97	0.57	1.97	0.57
Std. Deviation	0.315	0.924	0.374	0.769	0.551	0.750	0.651	0.559	0.750	0.584	0.600	0.603	0.645	0.555

BT= before treatment; AT= after treatment

Table 4. Changes in Allergic Rhinitis (AR) Clinical Status on severity of symptoms and total nasal symptom score (TNSS) after 60 days of treatment by *Pratimarsha Nasya* with *Anutaila* (n=37).

	Descriptive statistics about severity of symptoms and TNSS score									
	Rhinorrhoea		Nasal Obstruction		Sneezing		Nasal Itching		TNSS	
	BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
Mean	2.73	0.57	2.46	0.70	2.57	0.84	1.38	0.32	9.16	2.38
Std. Deviation	0.45	0.65	0.61	0.62	0.50	0.79	0.83	0.47	1.30	1.74

BT= before treatment; AT= after treatment

physicians providing consultations in an Ayurvedic tertiary care setting,between July, 2012 and December, 2013. The participants were selected from the out-patient department of Swasthavritta (Preventive and social medicine in Ayurveda), SDM College of Ayurveda and Hospital, Hassan, India.

Baseline assessment was made at the consultation, when the inclusion and exclusion criteria were checked by the physicians assessing each patient's history and allergic symptoms with full medical examination. The physicians were trained to use the instruments of assessment before the study. An observational, longitudinal study with a pretest and post test design of single group was designed with the aim of evaluating treatment response with Ayurvedic therapeutics in patients with AR in terms of changes in symptoms, and severity. The AR patients were treated as usual in daily clinical practice, where 37 patients were included after screening 45 patients. The patients were administered *Pratimarsha Nasya*with *Anutaila* daily for a period of 60 days.

The study was conducted according to current AYUSH (Ministry of Health and Family Welfare, Government of India) guidelines on good clinical practice (GCP) and the Declaration of Helsinki on Human Rights. The study was approved by the Institutional Ethics Committee and all participants gave their

Table 5. Changes in Allergic Rhinitis (AR) haematological parameters after 60 days of treatment by *Pratimarsha Nasya* with *Anutaila* (n=37).

Descriptive statistics on Haematological parameters								
	TLC		AEC		Neutrophils		Lymphocytes	
	BT	AT	BT	AT	BT	AT	BT	AT
Mean	8804.95	8628.76	476.49	389.62	61.65	57.42	35.62	32.65
Std. Deviation	384.838	341.36	49.03	37.78	5.73	5.48	3.72	3.24

BT= before treatment; AT= after treatment

Table 6. Effectiveness of *PratimarshaNasya*with *Anutaila* on Ayurvedic assessment parameters based on positive ranks after 60 days of treatment (n=37).

Wilcoxon Signed Ranks Test (Ayurvedic assessment criteria							
	Kshavathu	Tanusrava	Aanadhwa	Shirashoola	Gala shosha	Nistodashanka	Swarabheda
	AT - BT	AT - BT	AT - BT	AT - BT	AT - BT	AT - BT	AT - BT
Mean Rank	19	19	18	14	13	16.5	16
Z	-5.402*	-5.379*	-5.234*	-4.730*	-4.506*	-5.050*	-4.960*
Asymp. Sig. (2 tailed)	0.001	0.001	0.001	0.001	0.001	0.001	0.001

*Based on positive ranks;
BT= before treatment; AT= after treatment

written informed consent.The procedure of *Anutaila Pratimarsha Nasya* is very simple and patients were taught to instill two drops of *Anutaila* every day morning and evening to both nostrils and to spit the oil when it reaches the throat.

Inclusion Criteria: All participants were aged ≥18 years, had a history ofseasonal allergic rhinitis for at least a year, and fulfilled the seasonal allergic rhinitisdiagnostic criteria i.e. presence of all the following symptoms: sneezing, rhinorrhoea, itching (nose or eyes), and nasal congestion. Severity of at least two of above symptoms must be rated >2, where 0 = none, 1 = mild, 2 = moderate, 3 = severe, and 4 = very severe.

Exclusion Criteria: patients who gave a history of history of alcohol or substance abuse; were pregnantor breast feeding; had parasitic disease; perennial rhinitis or asthma sufficient to warrant regular topicalcorticosteroid treatment; had taken cortico-steroids in the past two months, antihistamines in thepast six weeks, or anti-inflammatory in the past twoweeks; who had received any immunotherapywithin the previous 12 months,

Table 7. Effectiveness of *Pratimarsha Nasya*with *Anutaila* on primary outcome measures after 60 days of treatment (n=37).

Paired Samples Test (Outcome Measures)				
Outcome measures (BT – AT)	**Mean difference**	**Std. Deviation**	**Std. Error Mean**	**Sig. (2-tailed (p-value)**
TLC	176.189	92.288	15.172	.001
AEC	86.865	23.613	3.882	.001
Neutrophils	4.22973	2.17177	0.35704	.001
Lymphocytes	2.97297	1.38417	0.22756	.001
TNSS	6.78378	2.08347	0.34252	.001

BT= before treatment; AT= after treatment

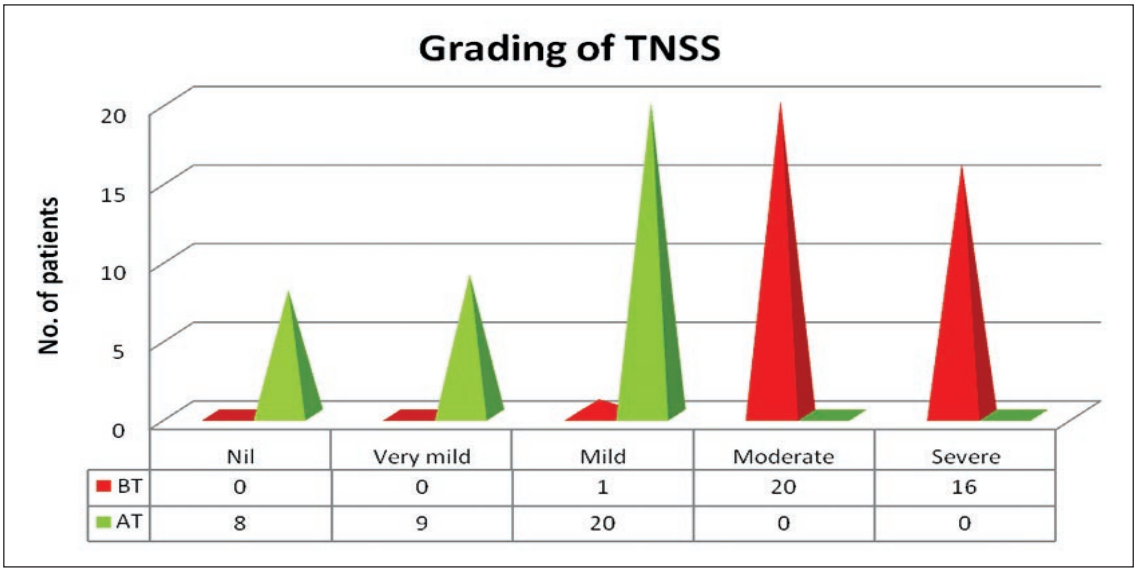

Fig. 1: Changed AR clinical status graded according to TNSS after 60 days of *Pratimarsha Nasya* with *Anutaila* treatment (n=37).

who gave a historyof cardiovascular disease or other importantmedical condition, who showed an appreciable degreeof nasal airway obstruction or polyp formation, or who were currently taking or had recently taken anti-depressant or antipsychotic drugs and had serious concomitant diseases.

Outcome Measures: Improvement was assessed once in 15 days with following subjective parameters for two months, but efficacy was tested only after completion of treatment *i.e.* after 60 days. Subjective

parameters – severity of symptoms assessment according to Ayurvedaand total nasal symptom score (TNSS) shown in Table 1 and 2 respectively.Patients evaluated the intensity of AR nasal symptoms (rhinorrhoea, nasal itching, nasal obstruction, and sneezing) and Ayurvedic severity of symptoms. Assessments were done by using a 4-point Likert scale. The total nasal symptom score (TNSS) was obtained from the sum of all 4 individual symptom scores,with a total possible score ranging from 0 (no symptoms) to 12 (maximum symptom intensity). Objectiveparameters – Blood haemogramdone before and after study included Total Leucocyte Count (TLC), Absolute Eosinophil Count (AEC), Neutrophils and Lymphocytes.

Drugs used and medication preparation: Using original standard material an Ayurvedic Pharmacy prepared the drug *Anutaila* according to the Ayurvedic Formulary of India (AFI).

RESULTS AND DISCUSSION

Age wise distribution of the 37 participants showed mean age of 35 ± 9.93 (SD) years; 40.54% (n=15) belonging to the age group between 17 – 37 years. Sex wise distribution showed 56.8% (n=21) participants were female and rest 43.2% (n=16) were males. Majority of participants (59.5%; n=22) were Hindu with 35.1% (n=13) belonging to Islam and rest 5.4% (n=2) were Christian. By nature of work 37.84% (n=14) were homemakers, 27% (n=10) were having agriculture as their main profession with 13.5% (n=5) being factory workers in jute mills. On the other hand 10.8% (n=4) and another 10.8% (n=4) were students andemployees in different govt. and non-govt. organizations respectively. Participants residing in semi-urbanized zone were 56.76% (n=21) and the other 43.24% (n=16) lived in villages. Family history of AR (*Vataja Pratishyaya*) was recorded in 24.3% (n=9) participants with. *Prakriti* (Ayurvedic genotype) showed *Pitta-Kapha* dominancy in 43.2% (n=16) participants, additional 35.1% (n=13) and 21.6% (n=8) were having *Kapha-Vata* and *Vata-Pitta Prakriti* respectively. Effect of *Pratimarsha Nasya* with *Anutaila*on the chief complaints assessed on Ayurvedic parameters showed marked improvement (Table 3). Progressive changes in AR clinical status on severity of symptoms and TNSS werealso observed among the participants (Table 4).After 60 days of treatment, the proportion of patients classified as symptom less, very mild, or mildwas 21.6%, 24.3%, and 54.1%, respectively. Figure 1 depicts the no. of patients having changed AR clinical status graded according to no symptoms, very mild, mild, moderate and severe. Statistics on haematological parameters also showed marked recovery of TLC and AEC counts after the therapeutic procedure (Table 5). Statistical significance (< 0.001) was noted for all the clinical and biochemical parameters. Wilcoxon Signed Ranks Test provided the z-score and p-value for the symptoms on Ayurvedic parameters (Table 6). This shows that there is a significant difference between before and after symptomatic relief of AR at significance level of 5% and *Pratimarsha Nasya* with *Anutaila* was effective in reducing the chief symptoms. The paired t test on biochemical parameters and TNSS provided the t value and p value depicted in table 7showing the high significance at the level of < 0.001 to be considered statistically significant.Analysis of the main outcome measures which included haematological parameters (TLC, AEC, Neutrophils and

Eosinophils) and TNSS rejected the hypothesis of *Pratimarsha Nasya* with *Anutaila*being ineffective byproviding strong evidence that the difference in before-after values is due to the effectiveness of Ayurvedic therapeutics in management of AR.

AR affects up to one third of the adult population, hence having a major socio-economic impact. In spite of the high prevalence and the availability of effective evidence-based therapeutics patients are still deprived of accurate diagnosis, symptomatic relief and specific anti-allergic treatment (Papadopoulos *et al.,* 2012).Also little is known about the patients' perceived knowledge level, expectationsand preferences for treatment and fear for side effects of treatment for AR (Hellings *et al.,* 2012). The treatment goal for AR is relief of symptoms. Therapeutic options available to achieve this goal include avoidance measures, oral antihistamines, intranasal corticosteroids, leukotriene receptor antagonists, and allergen immunotherapy. Other therapies that may be useful in select patients include decongestants and oral corticosteroids (Small and Kim 2011).

Novel drug delivery system is an ongoing field of research. In that context, nasal drug delivery system has a great potential in treating diseases like allergic rhinitis, COPD etc. The current research showed the traditional application of nasal drug delivery system with considerable safety and efficacy. The present study was an effort aimed at the therapeutic effect of Ayurvedic procedure *i.e. Pratimarsha Nasya* with *Anutaila* in AR. Purposively selected 37 patients were included for the treatment. A scoring method was adopted for the symptoms for evaluation of effectiveness according to Ayurvedic therapeutic principles where marked improvements were observed for the symptoms with statistical significance (< 0.001). TNSS, TLC and AEC also showed marked improvement with statistical significance (< 0.001).The excellence rate was 21.6% patients got complete relief.

Study from Switzerland and Germany showed effects of butterbur are similar to those of cetirizine in patients with seasonal allergic rhinitis. Concluding that Butterbur should be considered for treating seasonal allergic rhinitis when the sedative effects of antihistamines need to be avoided (Schapowal 2002). Studies found a significant difference in outcome measures (symptom scores, symptom-free days, and recourse to symptom relieving drugs) where enzyme potentiated desensitization administered by a single pre-seasonal injection found efficacious in reducing hay fever symptoms (Radcliffe *et al.,* 2003).

Study conducted in Korea ona poly-herbal medicine in ovalbumin (OVA)-induced allergic rhinitis (AR) guinea pigs demonstrated to be regulating allergic inflammation in AR by inhibiting nasal damage, the release of allergic mediators and modulating the balance of Th1/Th2 cytokines (Jung *et al.,* 2012). Another study on Traditional Chinese Medicine on guinea pigs showed that inhalation of CTCM could abolish the increased lung resistance along with increased levels of IgE, total leukocytes,eosinophils and neutrophils, thereby reducingthe inflammatory cells and the interleukin-5 (IL-5) level in BALF (Chang *et al.,* 2011).

Allergen specific sublingual immunotherapy (ASSIT) in PAR influences the Intracellular expression of IFN- gamma and IL-4 by CD3+CD8+ T-cells. A study showed the favorable clinical response induced by ASSIT

in PAR correlated with the decrease in the percentage of Tc2 cells and the increase in the percentage of Tc1 cells (Mahmod *et al.*, 2012). Also a recombinant humanized construct of a murine antibody that binds to circulating IgE was found safe and effective in controlling birch pollen–induced SAR symptoms, with less concomitant medication use, improved QOL and thus highlighted the therapeutic potential of anti-IgE antibody in SAR (Ädelroth *et al.*, 2000).

Allergic rhinitis is linked strongly with asthma andconjunctivitis.Allergen skin testing is the best diagnostic test toconfirm allergic rhinitis. Intranasal corticosteroids are the mainstay of treatmentfor most patients that present to physicians withallergic rhinitis. Allergen immunotherapy is an effective immunemodulatingtreatment that should be recommended ifpharmacologic therapy for allergic rhinitis is not effectiveor is not tolerated (Small and Kim 2011).

Disturbingly AR prevalence and impact are on the rise, a development that has been associated with environmental and lifestyle changes accompanying the continuous process of urbanization and globalization. Therefore, there is an urgent need to prioritize and concert research efforts in the field of allergy, in order to achieve sustainable results on prevention, diagnosis and treatmentof this most prevalent chronic disease of the 21st century. Since there is lacking of evidence based and holistic approach in field of allergy there is a constant need for promoting excellence in clinical care, education, training and basic and translational research, all with the ultimate goal of improving the health of allergic patients. Although allergies may involve almost every organ of the body and an array of diverse external factors act as triggers, there are several common themes that need to be prioritized in research efforts. As in many other chronic diseases, effective prevention, curative treatment and accurate, rapid diagnosis represent major unmet needs.

Ayurveda can reach out for the most important research needs in the field of allergy to serve as key recommendations for future research with efforts to unveil the basic patho-physiologic pathways and mechanisms, thus leading to the comprehension and resolution of the patho-physiologic complexity of allergies will allow for the design of novel patient-oriented treatment protocols. Several allergic diseases require well-controlled epidemiological description and surveillance, using disease registries, pharmaco-economic evaluation. Additionally, there is a need for extensive studies to bring promising new biotechnological innovations in a holistic approach closer to clinical practice. Finally, particular attention should be paid to the difficult-to-manage, precarious and costly severe disease forms and/or exacerbations. Nonetheless, currently arising treatments, mainly in the fields of immunotherapy, biological with traditional system of medicine holds great promise for targeted and causal management of allergic conditions. Active involvement of all stakeholders, including Patient Organizations and policy makers are necessary to achieve the aims emphasized.

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