

## A Study of Clinical Profile and Therapeutic Modalities in Patient with Allergic Rhinitis in Imphal, India

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### **Abstract:**

**Background:** Allergic Rhinitis is one of the commonest atopic diseases with greater morbidity and significant social and economic burden. The new classification given by Allergic Rhinitis and its Impact on Asthma is according to its severity and duration.

**Objective:** To study the effect of allergic rhinitis using Allergic Rhinitis and its Impact on Asthma (ARIA) definitions to determine its severity and to determine the effectiveness of Drugs in the aspect of symptom control and better quality of life and determine percentage of case requiring surgery for their anatomical abnormalities causing obstruction.

**Methods:** Patients with clinical diagnosis of allergic rhinitis presented with two or more nasal symptoms of excessive sneezing, watery nasal discharge, nasal congestion and itching of nose and eyes in all age group and sex were taken in study. According to severity, the patients were divided into the mild groups and the moderate-severe groups. The patients were given questionnaires on allergic rhinitis related symptoms. The total day time nasal symptom score was calculated by adding the individual scores for the four characteristics symptoms of allergic rhinitis. Data of pretreatment and post treatment were collected using pre-tested coded questionnaire and analysis using IBM SPSS statistical computer software version 21.

**Results:** The mean age of subject was 28.3 years, majority of age group 21 to 30 years. Male constitute 55% and female 45%, 66% of the subjects were suffering from seasonal and 34% from perennial. 42.4% were symptomatic during winter followed by monsoon 31.8% and summer 25.8%. Majority of patient 67% had moderate to severe AR and 33% had mild AR as per ARIA classification. Total nasal symptom scores decreased from baseline mean 6.08 to 1.29 after treatment ( $P < 0.001$ ). Inferior turbinate hypertrophy, adenoid hypertrophy, nasal polyps, otitis media, sinusitis and asthma constitute 57% of comorbidities. Only 13% of patients required surgery for associated comorbidities causing nasal obstruction.

**Conclusion:** Moderate to severe symptom were the one who comes to consult physician thus a study in general population is needed to assess the prevalence. Intranasal nasal spray of azelastine and fluticasone was effective in managing the symptoms. Most of the patient of Allergic rhinitis and its comorbidities can be treated conservatively and surgery is required for only few patients for anatomical abnormality because of comorbidity causing nasal obstruction.

**Key Words:** Allergic rhinitis, ARIA, Treatment outcome

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### **I. Introduction**

Allergic Rhinitis (AR) is an IgE-mediated immunological response of nasal mucosa to air-borne allergens and is characterized by watery nasal discharge, nasal obstruction, sneezing and itching in the nose. This may also associated with symptom of itching in the eyes, palate and pharynx as the mucosal lining of the nose is continuous with the Para nasal sinuses which may also get involved [1].

In allergic rhinitis the early or immediate phase response occurs in sensitized individuals within min of exposure to the allergen and lasts for about hours. One of the cardinal components of the early phase response is the degranulation of mast cells and releases histamine, which is the major mediator of allergic rhinitis, stimulates the sensory nerve endings and induces sneezing. It also stimulates the mucous glands causing the secretion of mucous (rhinorrhea). Histamine, leukotrienes and prostaglandins acts on the blood vessels causing nasal congestion. The early phase response is usually followed by the late phase response which response is characterized by a prolongation of symptoms sneezing, rhinorrhea but most predominantly a sustained nasal congestion which lasts for about 18-24 h. The late phase response is predominantly inflammatory in nature and is characterized by an inflammatory cellular influx comprising of predominantly T lymphocytes, basophils and eosinophils [2].

Allergic rhinitis is recognized as one of the most common otorhinolaryngological condition which has considerable effect on quality of life and can have consequences if left untreated. The burden of allergic rhinitis lies on impaired physical and social functioning and also in a financial burden for treatment of its co-morbid disease [3]. AR had been classified as seasonal, perennial or occupational AR according to the exposed

allergens [4]. The Allergic rhinitis and its impact on asthma (ARIA) group proposed a new classification based on the duration and severity of symptoms. AR is classified into the mild or moderate-severe groups according to the severity of symptoms and AR is also classified into the intermittent or persistent groups according to the duration of symptoms. Thus, AR is divided into four groups: the mild intermittent, mild persistent, moderate-severe intermittent and moderate-severe persistent groups [5].

Pharmacotherapy along with effective allergen avoidance measures forms the mainstay of modern management of allergic rhinitis. Antigens are not always avoidable and immunotherapy modifies the allergic response but not always afford protection from overwhelming antigen exposure. Therefore symptomatic management by means of pharmacotherapy is required for patient with allergic rhinitis [6]. The therapeutic options available for the treatment of allergic rhinitis are effective in managing symptoms and are generally safe and well-tolerated. Second-generation oral antihistamines and intranasal corticosteroids are the mainstay of treatment for the disorder [7]. Surgical management may be required for treatment of allergic rhinitis which is refractory to conservative treatment or has anatomical abnormality and for the treatment of associated co-morbidity [8].

Allergic rhinitis is one of the commonest atopic diseases which contribute to significant morbidity. However it has still does not receive the attention it deserves by the patients as well as, clinicians and the clinical characteristics of the patients with AR, according to the recent classification. The present study was hence, conducted with the aim to identify the clinical profile of the patients with AR and to find the severity of symptoms, other co-morbidities and treatment outcome.

## II. Materials And Methods

This was a Prospective clinical study included all patients with a clinical diagnosis of allergic rhinitis in the Department of otorhinolaryngology, Regional Institute of medical sciences (RIMS) Imphal: Manipur. The procedure and data collection was carried out for two calendar years with effect from September 2013 to August 2015. Patients with clinical diagnosis of allergic rhinitis presented with two or more nasal symptoms of excessive sneezing, watery nasal discharge, nasal congestion and itching of nose and eyes in all age group and sex attended Regional Institute of Medical Science ENT clinic and ENT wards during the study period. Patients with co-morbid conditions associated with allergic rhinitis like otitis media, nasal polyps, tonsillitis, hypertrophied turbinate and sinusitis were also included in the study.

Inclusion criteria: Patients presenting with sneezing, itching sensation of nose, watery nasal discharge and sensation of nasal obstruction which are hallmark of allergic rhinitis were taken up for the study irrespective of age and sex. Exclusion criteria: Those patients presenting with symptoms due to structural abnormalities such as grossly deviated septum, tumors etc. were not included. Used of systemic or oral corticosteroid within 30 days of the entry visit. Patient who were hypersensitivity to antihistaminic or corticosteroids were excluded from studies. Patients with systemic illness like severe heart disease, severe psychiatric illness, pregnancy and other acute infection and patients unwilling to give their consent.

A brief history will be taken from all patients attending the ENT department and based on clinical symptoms individuals were diagnosed clinically as allergic rhinitis. The symptom severity will be scored on self-assessment scale of 0 to 3 for four cardinal symptoms of allergic rhinitis. Namely: sneezing, itching, nasal obstruction and rhinorrhea.

- Grade 0: No symptoms : Asymptomatic.
- Grade 1: Mild symptoms : Symptoms do not interfere with daily activities and/or sleep.
- Grade 2: Moderate symptoms : Symptoms enough to interfere with daily activities and/or sleep.
- Grade 3: Severe symptoms : Symptoms are so pronounced that the patient cannot function properly during the day and/or sleep even with present treatment.

### Day Time Nasal Symptom Score

Within the last one month how did the following problem affect you?

Sneezing	0	1	2	3
Itching	0	1	2	3
Nasal obstruction	0	1	2	3
Watery rhinorrhea	0	1	2	3

The total day time nasal symptom score was calculated by adding the individual scores for the four characteristics symptoms of allergic rhinitis. Eye symptoms of itching, watering and redness were recorded as absent or present. According to severity, the patients were divided into the mild groups and the moderate-severe groups. Data were collected using a pre-tested coded questionnaire and physical examination. Data administered in the questionnaire included; patients characteristics (e.g. age, sex, occupation), nasal symptoms, eye symptoms, age of onset of symptoms, triggering factors, presence or absence of family history of allergic

rhinitis and asthma, presence of co-morbidity and the effects to the quality of life (defined as interference with daily activities and sleep disturbances). Appropriate examination was done to all patients.

All patients with no co-morbidities were treated conservatively with intra nasal corticosteroids (Fluticasone) and antihistamine (Azelastine) and selected patients with co-morbidities were operated accordingly.

Active Ingredient: Azelastine hydrochloride and fluticasone propionate.

Dosage Form; Route: Spray, metered/nasal

Strength: 137 mcg/50 mcg per spray

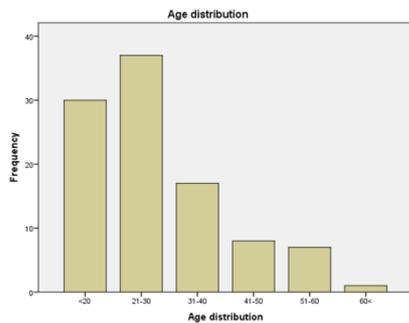
Dose: two sprays per nostril (548 mcg azelastine hydrochloride and 200 mcg fluticasone propionate).

Patients were followed up until the day of discharge. After discharge patients were followed up at our ENT clinic for one month (30 days) period. Efficacy of drugs will be assessed during weekly follow up by relief of symptoms. At each visit, the patients were asked to rate the severity of their nasal symptom and ocular symptoms. Statistical data analysis: Data was analyzed using IBM SPSS software version 21.0 with the guide of medical statistician. Data was summarized in the form of proportions frequency tables, bar and pie charts for categorical variables. Non parametric tests were used since the assessments were in symptom severity scores. Post treatment changes of nasal symptoms were analysis by Kendall's tau-b and post treatment changes of ocular symptoms were analysis by Mc Nemer test. Total Nasal Symptom Score was analysis using paired samples test. Significance was defined as a p-value of less than 0.05.

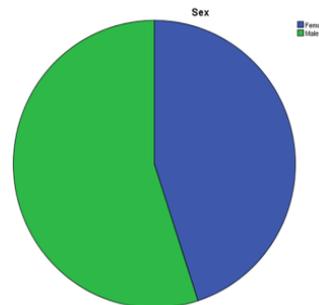
### III. Results

In this study age of patient ranges from 7 to 63 years. The highest numbers of patients were seen in the age group of 21 to 30 years with 37 patients. It was followed by the age group < 20 with 30 patients. Male were 55% and female 45% of patients. Mean age is 28.3years.

**Figure-1.**

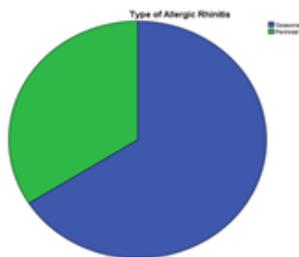


**Figure-2.**

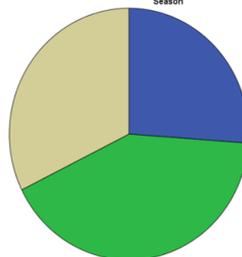


66% of the subjects were suffering from seasonal allergic rhinitis and 34% from perennial allergic rhinitis. Among the patients with seasonal allergic rhinitis majority of the patients 42.4% were symptomatic during winter followed by monsoon 31.8% and summer 25.8%. 33 patient present with mild symptom and 67 patients has moderate to severe symptom.

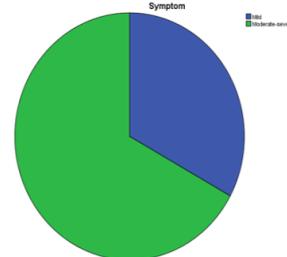
**Figure-2.**



**Figure-4.**



**Figure-5.**



Total nasal symptom score of all 100 patients in pretreatment maximum score was 9 and minimum was 1 with mean value of 6.08. After treatment maximum score was 3 and minimum was 0 with mean value of 1.29. Result shows that there were significant reductions in mean total nasal score from 6.08 to 1.29 (P<0.001).

**Table 1**

Total Nasal Symptom Score	N	Minimum	Maximum	Mean	Std. Deviation	p- value
Pre Treatment Score	100	1.00	9.00	6.0800	1.67983	.000
Post Treatment Score	100	0.00	3.00	1.2900	1.09448	

**Table 2**

Comorbidities	No of Patients	Percentage
Adenoid Hypertrophy	2	2%
Inferior Turbinate Hypertrophy	36	36%
Nasal Polyps	8	8%
Ear Discharge	3	3%
Sinusitis	5	5%
Asthma	3	3%
Total	57	57%

**Table 3**

Type of Surgery	No. of Patient	Percentage
Adenoidectomy	2	2%
Endoscopic Sinus Surgery	8	8%
Turbinectomy	3	3%
Total	13	13%

#### IV. Discussion

Allergic rhinitis is the most common immunological disease and highly prevalent chronic disease [9]. The prevalence is increasing in many western countries and disease burden is considerable with negative impacts on sleep, mood and social functioning, work or performance and health related quality of life. Allergic rhinitis is now a global health problem and can no longer be neglected by healthcare since its burden is associated with direct health resource costs and indirect socio-economic cost (e.g. absenteeism and loss of productivity) [10].

This study included 100 patients who attended ENT outpatient department in our hospital during the study period and clinically diagnosed as allergic rhinitis. In our studies majority of the patients belonged to the age group of 21 to 30 years (37%) with mean age of 28.3 years, the incidence of mean age in accordance with the study of Saleem [11] 35.2 years and Kalpaklioglu [12] 32 years. This may be because the life style and activity in this age group as they are more active compare to older age group which increase the chances of bringing them into contact with wide variety of allergens.

In this study male constitute 55% and female 45% showing male predominance. In other studies too there was male predominance as reported in the literature [13,14]. However allergic rhinitis does not differ in its clinical presentation and treatment outcome between male and female.

Majority of patients (66%) has seasonal rhinitis and incidence is more in winter season. This may be because of dry and windy during winter and exposure to cold as majority of patient gives history allergy to dust and cold. Many patients with allergic rhinitis had family history of allergic rhinitis.

Following the ARIA guidelines it was observed that majority of the allergic rhinitis patients had moderate to severe. In this study out of 100 patients 67% of the subjects had moderate to severe allergic rhinitis according to ARIA classification. The severity of rhinitis had more effect on quality of life, sleep, daily activities and work performance than its duration. The imbalance in the numbers of patients according to severity may be because patients consult a physician for allergic rhinitis only when they have severe allergic symptoms. In the study conducted by Bachau and Durham [15,16] found that in the general population the majority of patients with allergic rhinitis have mild rhinitis.

In our study pretreatment nasal symptom scores, the sum of individual severity score of nasal blockage, rhinorrhea, sneezing and itching before beginning of treatment were used to represent the severity of nasal symptoms and analysis with post treatment symptom control. In the present study the assessment was done using a total nasal symptom scores. There were significant differences in symptom scores after treatment with azelastine and fluticasone nasal spray before treatment mean  $6.08 \pm 1.67$  and after treatment mean  $1.29 \pm 1.09$ ,  $p < 0.001$ . There was overall improvement in both nasal and ocular symptoms in our findings. This result is in accordance with other publications of intra nasal corticosteroids [17-19]. Ratner HP et al [20] in their study also found that significantly greater efficacy was achieved by combination therapy with an antihistamine nasal spray and an intranasal (corticosteroid) spray, when compared with either agent alone.

In the present study the comorbidities associated with allergic rhinitis were 57%. Patients with adenoid hypertrophy, nasal polyp and inferior turbinate hypertrophy had more severity of nose block and other comorbidities like asthma, otitis media, sinusitis and ocular symptoms also contribute its effect on the patient of

allergic rhinitis. Most of the patients were treated conservatively and 13 patients were treated surgically for nasal abnormality for nasal obstruction. The surgical indications in the present study were nasal polyp, adenoid hypertrophy and nasal obstruction due to hypertrophy of inferior turbinate. All operated patient were given intranasal steroid after discharge and follow up. The study shows the benefit of combined medical and surgical therapy for reducing nasal obstruction.

There are numbers of limitations in this study this includes absence of laboratory allergy testing and time bound, however despite these limitations, the study can help health care to develop guidelines for early detection and proper management of allergic rhinitis to reduce comorbidities and helps in further studies on allergic rhinitis.

## V. Conclusion

Allergic rhinitis is one of the commonest immunologic diseases experienced by human. In our study we found the disease to be common in younger age group and male predominance. Majority of subject suffers from seasonal rhinitis. Incidence is more in winter because of dry and dusty in these seasons. Moderate to severe symptom were the one who comes to consult physician thus a study in general population is needed to assess the prevalence of the four ARIA classifications of allergic rhinitis.

Intranasal nasal spray of azelastine and fluticasone was effective in managing the symptoms and used as combined nasal spray may provide a substantial clinical benefit. Most of the patient of Allergic rhinitis and its comorbidities can be treated conservatively and surgery is required for only few patients for anatomical abnormality because of comorbidity causing nasal obstruction.

## References

- [1] Scadding G, Durham S. Allergic rhinitis. In: Gleeson M, editors. *Scott-Brown's Otorhinolaryngology, Head and Neck Surgery* 7th ed. (London UK: Edward Arnold; 2008)1386-1407.
- [2] Pawankar R, Mori S, Ozu C, Kimura S. Overview on the pathomechanisms of allergic rhinitis. *Asia Pac Allergy*. 2011;1(3):157-67.
- [3] Nathan RA. The burden of allergic rhinitis. *Allergy Asthma Proc*. 2007;28(1):3-9.
- [4] Dykewicz MS, Fineman S. Executive summary of joint task force practice parameters on diagnosis and management of rhinitis. *Ann Allergy Asthma Immunol*. 1998;81(5):463-8.
- [5] Bousquet J, Khaltaev N, Cruz A, Denburg J, Fokkens WJ, Togias A, et al. Allergic Rhinitis and its Impact on Asthma (ARIA). *Allergy*. 2008;63 Suppl 86:8-160.
- [6] Mabry RL. Allergic rhinitis. In: Cummings CW, Fredrickson JM, Harker LA, Krause CJ, Schuller DE, Richardson MA, editors. *Otolaryngology Head and Neck Surgery* 3rd ed. 9Missouri USA: Mosby; 1998) 902-8.
- [7] Small P and Kim H. Allergic rhinitis. *Allergy Asthma Clin Immunol*. 2011;7(Suppl 1):S3
- [8] Yoo JB, Yoon JH. Surgical management of allergic rhinitis. *J Korean Med Assoc*. 2004;47(7):672-8.
- [9] Katelaris CH, Lee BW, Potter PC, Maspero JF, Cingi C, Lopatin A, et al. Prevalence and diversity of allergic rhinitis in regions of the world beyond Europe and North America. *Clin Exp Allergy*. 2012;42(2):186-207.
- [10] Meltzer EO, Bukstein DA. The economic impact of allergic rhinitis and current guidelines for treatment. *Ann Allergy Asthma Immunol*. 2011;106(2):12-6.
- [11] Saleem T, Khalid U, Rehman SU, Ghaffar S. Clinical profile, outcomes and improvement in symptoms and productivity in rhinitis patients in Karachi. *BMC Ear Nose Throat Disord*. 2009;9:12.
- [12] Kalpaklioglu AF, Baccioglu AJ. Evaluation of quality of life: impact of allergic rhinitis on asthma. *J Invest Allergol Clin Immunol*. 2008;18(3):168-73.
- [13] Bot CM, Moed H, Schellevis FG, Groot H, Wijk RG, Wouden JC. Allergic rhinitis in children: incidence and treatment in Dutch general practice in 1987 and 2001. *Pediatr Allergy Immunol*. 2009;20(6):571-7.
- [14] Alsowaidi S, Abdulle A, Bernsen R, Zuberbier T. Allergic rhinitis and asthma: a large cross-sectional study in the United Arab Emirates. *Int Arch Allergy Immunol*. 2011;153(3):274-9.
- [15] Bauchau V, Durham SR. Prevalence and rate of diagnosis of allergic rhinitis in Europe. *Eur Respir J*. 2004;24(5):758-64.
- [16] Bauchau V, Durham SR. Epidemiological characterization of the intermittent and persistent types of allergic rhinitis. *Allergy*. 2005;60(3):350-3.
- [17] Fabri NZ, Eduardo A, Zollner RL. Azelastine and budesonide (nasal sprays): Effect of combination therapy monitored by acoustic rhinometry and clinical symptom score in the treatment of allergic rhinitis. *Allergy Rhinol*. 2014;5(2):78-86.
- [18] Aneeza WH, Husain S, Rahman RA, Dort DV, Abdullah A, Gendeh BS. Efficacy of mometasone furoate and fluticasone furoate on persistent allergic rhinoconjunctivitis. *Allergy Rhinol*. 2013;4(3):120-6.
- [19] Ferguson BJ, Paramaesvaran S, Rubinstein E. A study of the effect of nasal steroid sprays in perennial allergic rhinitis patients with rhinitis medicamentosa. *Otolaryngol Head Neck Surg*. 2001;125(3):253-60.
- [20] Ratner HP, Hampel F, Bavel JV, Amar NJ, Daftary P, Wheeler W, et al. Combination therapy with azelastine hydrochloride nasal spray and fluticasone propionate nasal spray in the treatment of patients with seasonal allergic rhinitis. *Ann Allergy Asthma Immunol*. 2008;100(1):74-81.