International Journal of Science and Research (IJSR) ISSN: 2319-7064

Impact Factor 2024: 7.101

A Cross-Sectional Observational Study to Determine the Diagnostic Utility of Nasal Smear Eosinophilia and Serum Immunoglobulin E (IgE) Level in Allergic Rhinitis in Adult Population

Dr. Pooja A R¹, Dr. Sunil Pai², Dr. Chandaa VJ³, Dr. Rohini D Urs⁴

¹Adichunchanagiri Institute of Medical Science and Research Centre, B G Nagara, Mandya Email: mandyapoo22[at]email.com

²Srinivasa Institute of Medical Science and Research Centre, Mukka, Mangalore. Email: docsunilpai[at]email.com

³Subbaiah Institute of Medical Science and Research Centre, Holey Honnur road, Shivamogga Email: *chandaavj.05[at]gmail.com*

⁴Adichunchanagiri Institute of Medical Science and Research Centre, B G Nagara, Mandya Email: *rohiniurs21[at]gmail.com*

Abstract: <u>Background</u>: Allergic rhinitis (AR) is an IgE-mediated inflammation of nasal mucosa triggered by allergen exposure, affecting 10-40% of global population. Diagnosis relies on clinical history, symptoms like rhinorrhoea, nasal itching, sneezing, & pale bluish mucosa, & tests such nasal smear eosinophilia and elevated serum IgE. This study aimed to evaluate the diagnostic utility of these markers in clinically confirmed AR cases and assess nasal smear eosinophilia severity correlates with symptom severity. <u>Materials & Methods</u>:100 consenting adults (18-75 years) attending the ENT department were enrolled & divided into 50 cases (AR patients) and 50 age & sex matched controls. Nasal smears were collected from both nostrils, fixed, and stained with Leishman and H&E stains. Slides were examined under 1000X magnification; >5 eosinophils in 3-5 fields or 20-30 cells single finding indicated positivity, graded as mild, moderate, & severe. Serum IgE was measured via chemiluminescent immunoassay. <u>Results</u>: Mean age was 39.78±15.15 years (range 18-75). Cases had 46% males, 54% females. Mean IgE level was 364.14±339.42 IU/ml in group I vs. 100.62±34.60 in group II (p<0.001). The mean nasal smear eosinophil count was 14.56±17.43 in group I & and 1.32±8.21 in group II (p<0.001). Nasal smear eosinophilia showed 81.3% positive predictive value at >0.3/HPF. Symptom severity correlated well with eosinophilia grading. <u>Conclusions</u>: Nasal smear eosinophilia and serum IgE aid AR diagnosis, with serum IgE offering better sensitivity and comparable specificity. Nasal eosinophilia is highly specific and links to symptom severity, supporting its routine use.

Keywords: Allergic Rhinitis; Nasal Smear Eosinophilia; Serum IgE Levels

1. Introduction

Its IgE-mediated hypersensitivity reaction of the nasal mucosa, allergic rhinitis (AR) is a widely recognized disease entity with a reported prevalence of 10–30% in adults and up to 40% in children worldwide. In terms of related comorbidities, medical resources, and treatment costs, allergic rhinitis and its corollaries place a significant burden on society and the person. Significant quality of life impairment can result from allergic rhinitis. Symptoms of allergic rhinitis, a systemic illness, commonly include headache, fatigue, lethargy, and malaise. Nasal blockage, rhinorrhea, postnasal drip, headaches, and nose itching are typical presenting symptoms. Due to a lack of diagnostic criteria and symptom overlap, non-allergic rhinitis is typically difficult to distinguish from allergic rhinitis.

TYPES: In terms of clinical recognition, two types exist

- 1) **Seasonal Allergic Rhinitis**: When a patient is allergic to a particular plant's pollens, symptoms either occur during or shortly after that season.
- 2) **Perennial Allergic Rhinitis**: This condition has year-round symptoms.

There are four further classifications for allergic rhinitis;

Mild-intermittent, mild persistent, moderate-severe persistent, and moderate – intermittent. When symptoms appear < 4 days a week or < 4 weeks in a row, they are considered intermittent. More than 4 days per week and more than 4 weeks in a row are considered persistent symptoms. If there is no disruption to everyday activities, work, school, or sleep, and the symptoms are not bothersome, the condition is deemed light.

Symptoms: Nasal symptoms can include sneezing, nasal obstruction, anterior or posterior rhinorrhoea, and/or nose itching.³ Palate, postnasal drip, eye, throat, and cough irritation are other symptoms.38 Perennial allergy symptoms are not as bad as seasonal allergy symptoms. These consist of recurrent colds, a runny nose, mucosal oedema-induced minor sense loss, and postnasal drip.

Signs: Allergy signs can appear in the larynx, throat, ears, eyes, or nose.

Nasal signs: pale and oedematous nasal mucosa, which
may seem bluish, and transverse nasal crease, a black
line across the middle of the dorsum of the nose caused

Volume 14 Issue 9, September 2025 Fully Refereed | Open Access | Double Blind Peer Reviewed Journal www.ijsr.net

International Journal of Science and Research (IJSR) ISSN: 2319-7064

Impact Factor 2024: 7.101

- by persistent upward rubbing. The turbinate swells. There is a thin, watery, or mucoid discharge.
- 2) Ocular signs: these comprise dark circles beneath the eyes (allergic shiners), congestion and a cobblestone-like appearance of the conjunctiva, and oedema of the lids.
- 3) Otologic signs: serous otitis media due to Eustachian tube occlusion or retracted TM (tympanic membrane).
- 4) Pharyngeal signs: proliferation of submucosal lymphoid tissue resulting in granular pharyngitis.
- 5) Laryngeal signs: vocal cord oedema and hoarseness.

2. Objectives

To determine the diagnostic utility of nasal smear eosinophilia and serum IgE in clinically confirmed cases of allergic rhinitis.

To determine whether the severity grading of nasal smear eosinophilia has any association to the severity of symptoms in allergic rhinitis

3. Materials & Methods

This cross-sectional observational study was conducted at the Outpatient Department of ENT, to evaluate the diagnostic utility of nasal smear eosinophilia and serum IgE levels in allergic rhinitis among adults. The study involved a patients aged 18 to 75 years attending the ENT department. A total of 100 participants were enrolled and divided equally into two groups: Group I (cases) comprising 50 clinically diagnosed allergic rhinitis patients, and Group II (controls) with 50 age- and sex-matched individuals without allergic rhinitis symptoms.

Table 1: Showing Inclusion and Exclusion Criteria

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Inclusion Criteria	Exclusion Criteria:		
All adults aged 18-75 years.	Age 75 years.Recent (last month) acute or chronic respiratory infections.		
Cases: History of paroxysmal sneezing, nasal/eye/throat itching upon allergen exposure, watery nasal discharge, nasal obstruction, and clinical signs suggestive of allergic rhinitis.	 Asthma patients on current therapy. Pregnant or nursing women. 		
Controls: No symptoms or signs of allergic rhinitis, matched for age and sex	 Use of local/systemic anti-inflammatory drugs. Recent (preceding month) antihistamines, β2 agonists, or systemic/intranasal/inhaled corticosteroids. Snuff users. 		

- a) Study Design and Period: Observational analytical cross-sectional study spanning 2 years.
- **b)** Sample Size: 100 participants (50 cases, 50 controls).
- c) Data Collection: The study commenced after institutional ethics committee approval. Informed consent was obtained in the patient's preferred language. A detailed history was recorded using a custom proforma. Thorough medical history confirmed allergic rhinitis diagnosis based on symptoms like sneezing, rhinorrhea, nasal itching, and obstruction. Investigations, clinical features, and history were documented. Nasal smears and blood for serum IgE were collected from both groups.
- d) Nasal Smear Procedure: Samples were obtained from each nostril using a sterile cotton-tipped swab rubbed along the inferior turbinate 2-3 times, then smeared on a glass slide. Alternatively, nasal secretion was collected by blowing into plastic wrap and pressed onto a slide. At least two smears per participant were prepared: one fixed and stained with Leishman stain, the other with hematoxylin and eosin (H&E). A pathologist examined slides under light microscopy with oil immersion (1000X magnification). Eosinophil grading followed Indranil et al.²: Grade I (50%). Positive eosinophilia was defined as >5 eosinophils in 3-5 fields or 20-30 cells in one field, classified as mild, moderate, or severe.

Table 2: Showing Eosinophil grades

% Eosinophil in nasal smears	Grade
<5%	Grade I
6 – 10%	Grade II
11 – 50%	Grade III
>50%	Grade IV

e) Under aseptic conditions, 3 ml blood was drawn from the antecubital vein into a serum separator tube. chemiluminescent Analysed via automated immunoassay, results in IU/ml; >150 IU/ml elevated.

4. Results

The research design was a cross-sectional observational study with a sample size of 100 people. The objective was to examine the nasal smear eosinophil count and serum IgE levels in all the patients and determine the diagnostic utility of NSE and Serum IgE levels in detecting allergic rhinitis patients in group I (Cases).

Table 3: Age distribution of Cases (Group-1) with allergic rhinitis

Age	Number
18 - 30	18 (36%)
31 – 40	10 (20%)
41 – 50	11 (22%)
51 – 60	5 (10%)
61 – 70	5 (10%)
>71	1 (2%)

Mean age of patients was 39.78±15.15 ranging from 18-72 years in group. As per above data, 36% were in age group of 18-30 years which showed most prevalence and 22% were in the age group of 41-50 years and 20% were in the age group of 31-40 years and 10% in 51-60 years and 2% of age group was seen in >71 years which was least prevalent. Fifty controls were matched to similar age group of cases.

Table 4: Gender distribution in CASES (Group-1)

Gender	Number
Male	23 (46%)
Female	27 (54%)

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International Journal of Science and Research (IJSR) ISSN: 2319-7064

Impact Factor 2024: 7.101

The prevalence of allergic rhinitis was found to be higher in females (54%) than to males (46%) in this study.

Table 5: Distribution of symptoms in CASES (Group-1)

Signs & Symptoms	Cases
Anterior Rhinorrhoea	27 (54%)
Posterior Rhinorrhoea	17 (34%)
Paroxysmal sneezing	46 (92%)
Nasal block	33 (66%)
Itching nose	21 (42%)
Itching eyes	18 (36%)
Itching throat	16 (32%)
Loss of smell	10 (20%)

Paroxysmal sneezing was the most common symptoms for allergic rhinitis accounting for 46(92%) and 33(66%) patients had nasal block, 27(54%) were having anterior rhinorrhea, 21(42%) were having itching nose and least symptoms was loss of smell that is 10(20%).

Table 6: Grading of nasal smear eosinophilia in Cases & Controls

Controls		
Grading of NSE	Cases	Controls
Grade I (<5%)	3 (6%)	47 (94%)
Grade II (6-10%)	15 (30%)	2 (4%)
Grade III (11-50%)	29 (58%)	1 (2%)
Grade IV (>50%)	3 (6%)	0

Nasal smear eosinophilia (NSE) was assessed using Leishman and H&E staining, with positivity defined as >5% eosinophils. In cases NSE, graded as: 29(58%) cases had grade III eosinophilia and 15(30%) had grade II and 3(6%) each in grade I and grade IV. The mean nasal smear eosinophil count was 14.56 ± 17.43 in group 1 & and 1.32 ± 8.21 in group 2. The mean difference in both groups was statistically significant with p value was <0.001.

Table 7: Distribution of Cases & Controls based on Serum

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Serum IgE	Cases	Controls
>150 IU/ml	33 (66%)	0
<150 IU/ml	17 (34%)	50

Serum total IgE levels, measured via chemiluminescent immunoassay, that 33(66%) of cases had serum IgE levels more than 150 IU/ml and 17(34%) had less than 150 IU/ml. **Mean IgE level was 364.14±339.42 IU/ml in group I**. whereas None of the controls had raised serum IgE levels. Mean IgE levels in control group was 100.62±34.60. The mean difference in both groups was statistically significant with p-value was <0.001.

Table 8: Association b/n the severity grading and NSE with severity of symptoms

Grade of NSE	Sneezing	Nasal	Anterior
in cases		block	rhinorrhoea
Grade I	3	2	2
Grade II	15	8	9
Grade III	25	22	15
Grade IV	3	1	1

Most prevalent symptoms in cases were paroxysmal sneezing, nasal block and anterior rhinorrhea. These

symptoms were more found to be in patients of grade III nasal smear eosinophilia.

In the above data Grade III NSE patients had more severity grade with a percentage of 25 sneezing, 22 nasal block and 15 having anterior rhinorrhea. Grade II NSE were second most severity grade of 15 sneezing, 8 nasal block and 9 anterior rhinorrhea. And mild severity was seen in Grade I (3) with sneezing 3, Nasal block 2, Anterior rhinorrhea 2 and Grade IV (2), sneezing 3, Nasal block 1 and Anterior rhinorrhea 1.

This table shows that there is a good association between the severity grading of NSE with severity in symptomatology of allergic rhinitis. In group 1, 73.5% of patients were diagnosed with AR based on serum IgE levels, whereas 75.3% of patients had AR based on nasal smear eosinophilia. The difference in NSE and Serum IgE levels between the cases and controls group was statistically significant with a p value value < 0.001.

Perceptiveness, specificity, PPV and NPV of NSE were 88.7%, 80.1%, 81.3% and 75% respectively.

While serum IgE levels were 71.3% in group I male and 82.6% in group I female.

5. Discussion

The present study demonstrates the diagnostic utility of nasal smear eosinophilia (NSE) and serum IgE levels in patients with allergic rhinitis (AR). A significant correlation was found between NSE grading and symptom severity, supporting its role as a reliable diagnostic indicator. Serum IgE showed higher sensitivity, while NSE provided better specificity, indicating that their combined evaluation improves diagnostic accuracy.

In study conducted by **Sonawane R et al (2016)**⁴ on 100 patients, majority were men (n= 60) and 40 female. Exposure to dust was common risk factor for AR (81.7%) in their study.

Shruthi Gowthami M R et al ⁵ found that there was a strong correlation between the disease's severity and both NSE and IgE. The patients' average age was 35.2 years. 95.0% had total serum IgE raised above 100 IU/ml, and 81.6% had NSE >10%. Serum IgE and NSE exhibited a strong relationship with the degree of illness. The considerable increase in mean values of serum IgE and NSE with the severity of clinical score demonstrated a favourable association between these two variables and the clinical severity score. At p<0.05, it is statistically significant.

In a study done by **Pal I et al. (2017)**², showed NSE counts > 0.3 per HPF showed 100% PPV for AR and 100% Specificity. The diagnostic Nasal eosinophil count showed a sensitivity of 51.3%, specificity of 88.5%, positive predictive value of 87%, and negative predictive value of 54%. In nasal smears, eosinophilia was discovered in 44% of allergic patients and 30% of controls, respectively.

International Journal of Science and Research (IJSR) ISSN: 2319-7064

Impact Factor 2024: 7.101

These findings align with previous research highlighting the usefulness of cytology and immunological markers in differentiating AR from non-AR. The high prevalence of sneezing, nasal obstruction, and rhinorrhoea further emphasizes the burden of AR on quality of life. Unlike invasive and costly procedures such as skin prick testing, NSE and serum IgE are affordable, rapid, and non-invasive, making them suitable for outpatient and rural settings. Therefore, these parameters not only aid in accurate diagnosis but also serve as valuable tools for monitoring disease progression and response to therapy.

6. Conclusion

With a mean age of 39.78±15.15 and a range of 18 to 75 years, group 1 consisted of 23 (46%) males and 27 (54%) females. It has been shown that patients with stronger immune systems and younger ages are more susceptible to allergic rhinitis. The current study showed a 54% female preponderance and 68% exposure to pollen are most prevalent risk factor. This is likely due to the fact that women in our rural community, women were more likely to be housewives and were exposed to allergens, which during their house holds works makes their prevalence more noticeable. The results of this study showed that eosinophil counts in nasal smears are a very sensitive, but highly specific, method for diagnosing allergic rhinitis. Although nasal smear eosinophilia may not be specific to allergic rhinitis, a diagnosis of allergic rhinitis was found to be associated with NSE grading of Grade II and above. The most common symptom of allergic rhinitis was sneezing, which accounted for 92% of cases. Nasal blockage accounted for 66% of cases, and anterior rhinorrhoea accounted for 54%. Due to the social stigma associated with these symptoms, patients were found to be more concerned on minimizing these symptoms than on treating the allergic rhinitis itself. With an 81.3% positive predictive value, our study demonstrated that a nasal smears is an eosinophil count of >0.3 per HPF. At 80.12%, its specificity is a little bit low and highly specific criterion for the diagnosis of AR. There was a correlation between the nasal smear eosinophil levels and the severity of AR. Thus, we can conclude that the eosinophil levels in nasal smears are a moderate predictor of allergic rhinitis in patients. Other studies that have compared with NSE and skin prick test have demonstrated that it is highly specific and somewhat sensitive in this regard, which is why we recommend utilizing the nasal smear for eosinophilia to screen for and diagnose allergic rhinitis. As an inexpensive, non-invasive outpatient test, it can also be used to monitor a patient's response to treatment. It is essential to utilize less invasive and widely applicable tests, such nasal smear for eosionphilia, to quickly screen, diagnose, and monitor patients during the follow-up period in order to uncover uncharted territory in the treatment protocol of allergic rhinitis. Since there are multiple variants of rhinitis mimicking AR, it takes a thorough clinical history and examination to diagnose AR. Hence there is a need to distinguish AR and non AR in patients as it forms the basis for the need of finding the allergens to seek specific environmental controls and in-tern may help the patient to immunotherapy and other pharmacological treatments. NSE with Serum IgE are non-invasive, affordable and time saving tests to diagnosing between AR and Non-AR. This study discovers a strong association between nasal smear eosinophilia and allergic rhinitis, which is in line with many other studies. It was found that patients with allergic rhinitis were statistically more likely to have nasal smear eosinophilia.

IgE and eosinophils mediate allergic sensitization, the cause of allergy disorders. For individuals with allergic rhinitis, serum IgE level and nasal smear eosinophil count are straightforward, reasonably priced, and trustworthy first diagnostic criteria that enable therapy planning. Increased levels of serum IgE and nasal smear eosinophils were seen in patients diagnosed with allergic rhinitis in the current study, with a majority of females and younger age groups. Further studies may be required in larger masses to determine the specific roles of NSE and Serum IgE in patients response to pharmacological drugs or immunotherapy.

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Volume 14 Issue 9, September 2025
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