

A Comparative Study on Skin Prick Test and Laboratory Tests in their Accuracy to Diagnose Allergic Rhinitis

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Abstract

Background: To diagnose and confirm Allergic Rhinitis in addition to history taking and clinical examination an allergen-specific Immunoglobulin E antibody test or Percutaneous testing is necessary. Tests to study the reaction to specific allergens confirm the diagnosis is in vivo (skin prick tests) or in vitro tests (immunological tests).

Aim of the Study: To study the results of various diagnostic tests for allergic rhinitis among study groups. To study the sensitivity, specificity, accuracy and p value of the diagnostic tests.

Materials: 90 patients were divided into two groups with 45 in each and named group A and B. Group A consisted of Patients with clinical history of Allergic rhinitis and Group B with septal deviations, the later taken as control group. Skin prick test, absolute eosinophil count nasal smear eosinophil count and IgE were estimated in all. The diagnostic sensitivity, specificity and accuracy were calculated.

Results: The SPT possessed the highest sensitivity value of 93.18 and accuracy of 91.30 when compared to other tests like IgE values showed sensitivity value of 84.35 and accuracy of 85.60, AEC showed sensitivity value of 73.55 and accuracy of 69.10 and the lowest values were for Nasal smear eosinophils with specificity of 62.63 and accuracy of 64.20.

Conclusions: Skin Prick Test has the high specificity, sensitivity, and accuracy values in the diagnosis of Allergic Rhinitis when compared to in vitro diagnostic tools like blood tests (IgE), Eosinophil count of nasal smear, Absolute Eosinophil counts. But when they are combined the values of specificity, sensitivity, and accuracy will be improved. The Skin prick test should be further improved and standardized in the procedure and preparing the panels of the allergens based on the geographical areas of the patients.

Key words: Deviated nasal septum (DNS) Allergic rhinitis (AR), Skin prick test (SPT) and IgE.

INTRODUCTION

Allergic rhinitis is a systemic disease with local symptoms like excessive sneezing, watery discharge from the nose and itching of the nose and palate as early and nasal congestion as late response.^[1] It can also occur as a co-morbid condition of Bronchial Asthma.^[2] The burden of Allergic Rhinitis all over the World accounts for more than 12 million new cases

annually.^[3] Allergic rhinitis is categorized into three basic subgroups: seasonal, perennial, and occupational mediated by Ig E immunoglobulin.^[4] The pollens of Alp tree, different grasses, and weeds pollens usually cause seasonal Allergic Rhinitis.^[5] Seasonal and perennial Rhinitis is caused by moulds, *pet* allergens like dust mites, pet dander causing year long (perennial) symptoms.^[6] Exposure to chemical, noxious gases (formaldehyde, and hair spray) results in occupational Allergic Rhinitis which is non allergic type but seasonal.^[7] But allergen-related occupational rhinitis comes into the category of allergic rhinitis category due to lab animals, like rats, mice, grains, coffee beans, and wood dust and guinea pigs.^[8] Seasonal and perennial allergic rhinitis is usually associated with systemic symptoms like malaise, weakness, and fatigue.^[9] The diagnosis of Non-allergic Rhinitis is made after the IgE role is eliminated by investigation and it

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results due to acute viral infection.^[10] The other less common chronic Allergic rhinitis may be due to vasomotor rhinitis, hormonal rhinitis, non-allergic rhinitis with eosinophilia syndrome, occupational rhinitis (irritant subtype), gustatory rhinitis, rhinitis medicamentosa, and drug-induced rhinitis.^[11] Researchers showed that the prevalence of pure Allergic rhinitis among the adult population with symptoms was 43% and with combination of non-allergic rhinitis was 34%, and purely non-allergic rhinitis was 23%.^[12] As the treatment differs for Allergic and non-allergic rhinitis it is important and mandatory on the part of the physician to differentiate between these two conditions.^[13] Laboratory Testing to identify the specific allergens causing Allergic rhinitis helps in the confirmation of the diagnosis and to determine specific allergic triggers. It would also help in planning the appropriate treatment (desensitization) and preventive measures.^[14] Skin prick tests (immediate hypersensitivity testing) are the commonly used In vivo methods of determining allergy to a particular substance.^[15] These tests would help in identifying the sensitivity to virtually all of the allergens that cause allergic rhinitis (see Causes) can be determined with skin testing. In vitro diagnostic tests, like fluorescence enzyme immunoassay (FEIA), for example Immuno CAP, which indirectly measures the quantity of specific IgE to a particular antigen are used in few centers.^[16] Skin prick tests would give an immediate (early-phase) wheal-and-flare reaction.^[17] The test consists of scratching the epidermis under a droplet of allergen containing fluid placed on the volar aspect of the forearm.^[18] Total serum IgE estimation would also help the physician in grading the severity of the allergic rhinitis condition.^[19,20] The patients with Allergic rhinitis have an elevated total IgE level than the normal population but this test is neither sensitive nor specific for allergic rhinitis.^[21] The present study was conducted with an aim to study the Skin prick tests and Immunological tests were tried to verify their specificity, sensitivity, and accuracy in the diagnosis and confirmation of Allergic rhinitis (AR). These tests were also compared with blood tests and nasal smears.

TYPE OF STUDY

It was a cohort, prospective, non-randomized study.

PERIOD OF STUDY

April 2019 to March 2020.

INSTITUTE OF STUDY

Sri Siddhartha Institute of Medical Sciences and Research, T. Begur, Karnataka.

MATERIALS

90 patients attending the Department of ENT for the treatment of Allergic Rhinitis and Septal deviation were included and divided into two groups. In Group A the patients were those with symptoms and signs of Allergic Rhinitis (45 in number) and in Group B patients were those with deviated nasal septum (45 in number) were considered as control group. An ethics committee approval was obtained before commencing the study. An ethics committee approved proforma was used for the study.

Inclusion Criteria

Patients aged above 18 years and below 60 years were included. Patients of both the genders were included. Patients with all the symptoms and signs of Allergic Rhinitis were included. Patients with signs of Deviated nasal septum were included. Patients willing to undergo the study throughout were only included. Patients willing to undergo in vitro and in vivo tests for Allergy were included. Patients willing to undergo hematological tests were included. Patients willing to follow the treatment protocol of the Hospital were included.

Exclusion Criteria

Patients aged below 18 years and above 60 years were excluded. Patients with nasal diseases other than septal deviation and Allergic Rhinitis were excluded. Patients not willing to participate in the study protocol were excluded. Patients with co-morbid diseases like diabetes, hypertension, Bronchial Asthma and renal diseases were excluded. Patients who were pregnant were excluded. Patients with severe hypersensitive skin (dermatographism), patients using beta-blockers, patients not able to stop antihistamines were excluded. Patients who were pregnant were excluded. Patients with severe Bronchial Asthma were excluded. Patients with drug-induced rhinitis were excluded. Patients with cardiac disease in whom epinephrine could not be used were excluded. Patients included in the study were thoroughly explained regarding the purpose and method of the study. A written, informed consent was taken for all the procedures of In vitro and in vivo tests. Demographic data of the patients was recorded. A thorough clinical history and clinical examination including endoscopic examination of the nasal cavity was performed. Allergic Rhinitis scoring was done, for complete blood count, nasal smear eosinophil count, serum IgE levels. Skin Prick tests (SPT) with standard commercially available antigens like house dust, house dust mite, cotton dust, mixed pollens, mixed molds, housefly particles, and grass pollens in 50% Glycerine extract was used. One negative control with no allergen with 50% Glycerine, and one positive control containing histamine base 6 mg/ml, in a drop of solution on the volar part of the forearm of patient's skin and scratched with a sterile

needle only involving the epidermis, were conducted in all the subjects. Initially both the Positive and negative controls were used followed by the (positive) histamine control. A positive result was reported when a wheal of more than or equal to 3 mm developed on the forearm. The wheal was outlined with a sketch pen which was later blotted onto a cellophane tape and transcribed onto paper and stored electronically. Complete Blood Picture was performed to assess absolute eosinophil count (AEC) which denotes the total number of circulating Eosinophils in the peripheral blood (cells/mm³). If the count was more than 440 cells per mm³, then it was considered as positive. Nasal smear was collected on swab sticks from the inferior turbinate. Slide was prepared and fixed in 95% ethyl alcohol, stained with Haematoxylin and eosin stain. The test was reported positive if 10 or more Eosinophil cells were found by high power field ($E \geq 10/HPF$)^[21].

Statistical Analysis

The Qualitative data were presented as number, mean standard deviation and percentages. Chi square test was used to test the level of significance and correlation using SPSS software statistical computer package, version 18 (SPSS Inc., Chicago, Illinois, USA). Sensitivity, specificity tests were performed to differentiate diagnostic tests results of AR from the control group, with 95% confidence interval.

RESULTS

Among the 90 patients, who were divided into two groups, Group A was with 45 subjects and showed symptoms and signs of Allergic rhinitis (AR). Group B was used as a control group where in the patients were not having AR but septal deviation. Both groups were elicited of similar criteria in regards to medical treatment either of oral topical corticosteroids, or oral antihistamines four^[4] weeks prior to the first visit. In group A there were 13/45 (28.88%) patients aged between 18 and 27 years, 14/45 (31.11%) patients aged between 28 and 37 years, 08/45 (17.77%) patients aged between 38 and 47 years, 06/45 (13.33%) patients aged between 48 and 57 years, 04/45 (08.88%) patients aged between 57 and 60 years [Table 1]. There were 31/45 (68.88%) males and 14/45 (31.11%) female patients. Patients belonging to low socio-economic group were 20/45 (44.44%), middle income group were 17/45 (37.77%) and 08/45 (17.77%) patients were from high income group [Table 1]. BMI was between 25 and 30 Kg/m² in 26/45 (57.77%) patients, 30 to 35 Kg/m² in 10/45 (22.22%) patients and above 35Kg/m² in 09/45 (20%) patients. [Table 1] Patients from urban locality were 21/45 (46.66%) and 24/45 (53.33%) patients were from rural areas [Table 1].

Table 1: Shows the demographic data of the study (n-90; Group A-45; Group B-45)

Observation	Group A- 45	Group B-45	P value
Age			
18 to 27 years	13	16	0.152
28 to 37 years	14	18	
38 to 47 years	08	07	
48 to 57 years	06	04	
Above 57 years to 60 Yrs	04	00	
Gender			
Male	31	28	0.231
Female	14	17	
Socio-economy			
Low	20	18	0.311
Middle	17	16	
High	08	11	
BMI			
25 to 30 kg/m ²	26	24	0.517
30 to 35 kg/m ²	10	08	
>35 kg/m ²	09	13	
Locality			
Urban	21	26	0.623
Rural	24	19	

In group B there were 16/45 (35.55%) patients aged between 18 and 27 years, 18/45 (40%) patients aged between 28 and 37 years, 07/45 (15.55%) patients aged between 38 and 47 years, 04/45 (08.88%) patients aged between 48 and 57 years and there were no patients in the age group of 57 to 60 years [Table 1]. There were 28/45 (62.22%) males and 17/45 (37.77%) female patients. Patients belonging to low socio-economic group were 18/45 (40%), middle income group were 16/45 (35.55%) and 11/45 (24.44%) patients were from high income group [Table 1]. BMI was between 25 and 30 Kg/m² in 24/45 (53.33%) patients, 30 to 35 Kg/m² in 18/45 (40%) patients and above 35Kg/m² in 13/45 (28.88%) patients. (Table 1) Patients from urban locality were 26/45 (57.77%) and 19/45 (42.22%) patients were from rural areas [Table 1]. All the variable of both groups were almost similar and there was no statistical significant difference as the p value was more than 0.05 (p significant at <0.05).

In group A, skin prick test was positive in 33/45 (73.33%) patients and negative in 22/45 (48.88%) patients. The SPT was positive for various allergens was noted and displayed in the [Table 2]. Among the in vitro tests IgE values were between 1.5 to 144 IU/mL in 12/45 (26.66%) patients, between 150 to 300 IU/mL in 19/45 (42.22%) between 300 to 500 IU/mL in 14/45 (%) patients [Table 2]. Absolute Eosinophil count (AEC) less than 440 cells/mm³ was noted in 07/45 (15.55%) patients and more than 440 cells/mm³ was noted in 38/45 (84.44%) patients. Nasal smear for eosinophils was noted with less than 10 cells in 34/45 (75.55%) patients and more than 10 cells in 11/45 (24.44%) patients [Table 2].

In group B, skin prick test was positive in 09/45 (20%) patients and negative in 36/45 (80%) patients. The SPT was positive for various allergens was noted and displayed in the [Table 2]. Among the in vitro tests IgE values were between 1.5 to 144 IU/mL in 33/45 (73.33%) patients, between 150 to 300 IU/mL in 08/45 (17.77%) between 300 to 500 IU/mL in 04/45 (08.88%) patients [Table 2]. Absolute Eosinophil count (AEC) less than 440 cells/mm³ was noted in 39/45 (86.66%) patients and more than 440 cells/mm³ was noted in 06/45 (13.33%) patients. Nasal smear for eosinophils was noted with less than 10 cells in 37/45 (82.22%) patients and more than 10 cells in 08/45 (17.77%) patients [Table 2]. All the variable of both groups showed a statistical significant different values with a p value at 0.001 (p significant at <0.05).

After collecting the data from the subjects of group A and B, on the positive, negative, false positive and false negative test values in the diagnosis of Allergic Rhinitis, the sensitivity and specificity values were calculated using the standard equations. It was observed that SPT had a sensitivity value of 93.18 (89.20 to 96.50), specificity of 83.50 (78.15 to 87.50) with an accuracy of 91.30. For IgE values the sensitivity value was 84.35 (76.35 to 88.15) and specificity of 81.60 (75.40 to 86.15) with an accuracy of 85.60. For AEC values the sensitivity value was 73.55 (69.85 to 80.75) and specificity of 67.25 (60.90 to 71.30) with an accuracy of 69.10. For Nasal smear Eosinophils values the sensitivity value was 62.63 (56.10 to 73.55) and specificity of 62.85 (55.40 to 65.20) with an accuracy of 64.20 [Table 3]. All the diagnostic tests showed a significant association between the two groups with a p value at 0.001 (p significant at <0.05) [Table 3]. The SPT possessed the highest sensitivity value of 93.18 and accuracy of 91.30 when compared to other tests like IgE values showed sensitivity value of 84.35 and accuracy of 85.60, AEC showed sensitivity value of 73.55 and accuracy of 69.10 and the lowest values were for Nasal smear eosinophils with specificity of 62.63 and accuracy of 64.20 [Table 3].

DISCUSSION

Allergic Rhinitis is classically defined as a chronic inflammatory disease clinically characterized by excessive sneezing, watering of the nose and nasal obstruction preceded by itching of the nose and palate and eyes.^[22] The reported prevalence of AR in India is between 20% and 30%. The prevalence was found to be increasing alarmingly for the past two decades.^[23] Among the six Western studies, AR was found to be prevalent in 23% of their populations and nearly another 45% of the populations were undiagnosed and confirmed at the time of receiving prescriptions by their physicians.^[24] SPT was

Table 2: Shows the Diagnostic test values in both the groups (n-90; Group A-45; Group B-45)

Diagnostic tests	Group A- 45	Group B-45	P value
<i>In Vivo Test</i>			
Skin Prick test			
Positive	33	09	0.001
Negative	12	36	
Allergens			
House dust	10	01	0.001
House dust mite	05	03	
Cotton dust	04	01	
Mixed pollens	03	03	
Mixed molds	02	01	
Housefly particles	04	00	
Grass pollens	02	00	
Woolen dust	03	00	
<i>In Vitro Tests</i>			
IgE values			
1.5 to 144 IU/mL	12	33	0.001
150 to 300 IU/mL	19	08	
300 to 500IU/mL	14	04	
AEC			
<440 cells/mm ³	07	39	0.001
> 440 cells/mm ³	38	06	
Nasal smear Eosinophils			
< 10 cells/HPF	34	37	0.001
>10 CELLS/HPF	11	08	

Table 3: Shows the sensitivity and specificity of the *In vitro* and *In vivo* tests of Allergic Rhinitis (n-90; Group A-45; Group B-45)

Tests	Sensitivity (95 CI)	Specificity (95 CI)	Accuracy (95 CI)	P value
Skin Prick test	93.18	83.50	91.30	0.001
Ig E values	84.35	81.60	85.60	0.001
AEC value	73.55	67.25	69.10	0.001
Nasal smear Eosinophils	62.63	62.85	64.20	0.001

first described by Ebruster in 1959 and since then it is being used as a in vivo diagnostic tool in the diagnosis of type I hypersensitivity reaction of AR; many modifications and an array of interpretations have crept in which has now led to reduced comparability reports.^[25] Heinzerling *et al*^[26] adopted Global Allergy and Asthma European Network (GA (2) LEN) protocol while reporting and found that SPT was showing sensitivity of 80 to 97% and specificity of 70 to 95% especially in diagnosing respiratory allergens. Certain studies have observed that the clinical history taking alone would be useful as positive predictive value in the diagnosis of AR in only 77% of chronic patients and 82–85% in the cases of seasonal allergy. Such values would be improved to 97 to 99% if SPT was added to clinical history taking.^[27] In the present study the SPT possessed the highest sensitivity value of 93.18 and accuracy of 91.30

when compared to other tests like IgE values showed sensitivity value of 84.35 and accuracy of 85.60, AEC showed sensitivity value of 73.55 and accuracy of 69.10 and the lowest values were for Nasal smear eosinophils with specificity of 62.63 and accuracy of 64.20 [Table 3]. In another study by Nevis *et al.*^[28] the sensitivity and specificity of SPT were found to be in the range of 88.4 and 77.1%, respectively. When the sensitivity and specificity of nasal smears, AEC and IgE values were compared to SPT values, they were found to be lower. Mostofo *et al.*^[29] noted similar sensitivity and specificity values when they compared the SPT versus laboratory tests in the diagnosis of AR. In this study the mean IgE values and the sensitivity value was 84.35 (76.35 to 88.15) and specificity of 81.60 (75.40 to 86.15) with an accuracy of 85.60. In a similar study by Ansari *et al.*^[30] the sensitivity and specificity values of the tests for IgE were comparable to this study. Accurate identification of the specific allergen will help the physician in planning the management of AR and perennial rhinitis patients in the form of immunotherapy, allergen avoidance, or pharmacotherapy. This would also help the patient in lessening the financial burden of treatment. The present study favours SPT as the accurate and choice of diagnostic tool in the management of Allergic Rhinitis patients similar to previous studies. Although the present study was conducted on a small sample of subjects and comparing the SPT values with control group of septal deviation patients, further studies are required to compare all the diagnostic tools.

CONCLUSION

Skin Prick Test has the high specificity, sensitivity, and accuracy values in the diagnosis of Allergic Rhinitis when compared to in vitro diagnostic tools like blood tests (IgE), Eosinophil count of nasal smear, Absolute Eosinophil counts. But when they are combined the values of specificity, sensitivity, and accuracy will be improved. The Skin prick test should be further improved and standardized in the procedure and preparing the panels of the allergens based on the geographical areas of the patients.

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