International Journal of Health Sciences and Research
www.ijhsr.org ISSN: 2249-9571

Original Research Article

Diagnostic Accuracy of sIgE, Total IgE and Eosinophils Percentage among Patients with Asthma, Allergic Rhinitis, and Atopic Dermatitis in Saudi Arabia

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Received: 28/08/2016 *Revised: 19/09/2016* *Accepted: 22/09/2016*

ABSTRACT

Background: Assessment of sIge level, total IgE level and eosinophils percentage are the common markers used for diagnosis of atopic and allergic patients. This study aimed to assess the diagnostic accuracy of allergy markers included sIgE, total IgE testing and eosinophils percentage in the diagnosis of allergic diseases, in reference to final clinical diagnosis.
Materials and Methods: This retrospective study included 130 patients were randomly selected from the electronic records of patients suspected for allergy based on a history of significant respiratory or skin reaction and live in Jeddah city. Total IgE level was assessed using Unicap 100, while the assessment of specific IgE was conducted by the ImmunoCAP technology. The pooled analysis was done to calculate clinical sensitivity, specificity, positive and negative predictive values for the studied allergy markers.
Results: The sensitivity and specificity of sIgE assay were found to be 87% and 100% in comparison to 79% and 93% of total IgE assay and 70% and 100% in eosinophils percentage respectively. In addition, positive and negative predictive values of sIgE were found 100% and 69.8% in comparison to 97.5% and 57.1% of total IgE respectively. While positive and negative predictive values of eosinophils percentage were found 100% and 50% respectively.
Conclusions: In conclusion, the clinical sensitivity was very good in sIgE, good in total IgE but fair in eosinophils percentage, while the clinical specificity was excellent in all of these allergy markers. Positive predictive value was excellent in all allergy markers, but negative predictive value ranged from fair value in sIgE to poor value in eosinophils percentage.

Keywords: Allergy; asthma; IgE; eosinophils; sensitivity; specificity.

INTRODUCTION

Atopy is known as a tendency of immune system to produce excessive amount of immunoglobulin E antibodies upon exposure to the allergens. [1] Atopic patients usually complains of eczema until 3 years old, and then they affected by allergic asthma and rhinitis later on the age. [2] The association between development of allergic response with sensitization to different allergens, such as pollens and dust mites, was identified in many epidemiological studies. [3,4] In regards to asthma, indoors allergens found to be strongly associated with asthmatic symptoms where the odds ratio found to be in the range of 6.2 for cat hair [5] to19.7 for dust mites. [6]

This sensitization process was defined as type I hypersensitivity reaction that mediated by IgE, which mainly coordinates the immune response against protozoal infections. [7] The clinical manifestations of this reaction could present as allergic rhinitis, allergic asthma, allergic dermatitis, food allergy, and allergy to insect bites. [8] Additionally, eosinophils

have found to play a critical role in allergic response to various aeroallergens. Thus, the eosinophils percentage, as well as, assessment of IgE level is routinely used for the diagnosis of allergic patients. [9,10]

The level of serum IgE is normally variable among healthy people, however it is partially related to the age where levels less than 10 IU/ml were detected among infants to a level of 122.1 kU/L that was found among adults. [11,12] Atopic patients with allergic rhinitis, asthma, and allergic dermatitis usually presented with elevated levels of IgE in the absence of protozoal infections. [13] A cut off point of 195 IU/ml for IgE level is usually used in Saudi Arabia as an indicator for diagnosis of allergic diseases. [12] The ImmunoCAP immunoassay is considered the gold standard test that has been used to assess the level of specific IgE, however this assay is expensive and needs high technical skills. Thus, numerous clinicians use initially the total IgE level to assess the allergic reaction among suspected patients. [13,14] Despite the questionable accuracy of total IgE testing, many specialists in Arabic countries as well as in Saudi Arabia, are widely used the total IgE for diagnosis of allergic diseases. [12] In asthmatic patients, a significant association was detected between the number of activated eosinophils and the intensity of the symptoms and bronchial hypersensitivity. [15] Thus, assessment of sIge level, total IgE level and eosinophils percentage are the common markers used for diagnosis of atopic and allergic patients. [16] This study aimed to assess the diagnostic accuracy of allergy markers included sIgE, total IgE testing and eosinophils percentage in the diagnosis of allergic diseases, in reference to final clinical diagnosis.

MATERIALS AND METHODS

This retrospective study included 130 patients who were randomly selected from the electronic records of suspected allergic patients. These patients were presented between January 2014 and December 2015 to the outpatient or inpatient clinics of King Abdulaziz University Hospital (KAUH). KAUH is the referral medical center in the western region of Saudi Arabia. Only patients suspected for allergy based on a history of significant respiratory or skin reaction who were living in the city of Jeddah were included in this study. Jeddah is a coastal city located in the western region of the Kingdom of Saudi Arabia on the Red Sea, and high humidity characterizes its weather, particularly in the summer season. Any patient tested to total IgE assay, eosinophils percentage and specific IgE level were included. Smokers, diabetics, patients with protozoal infections, tuberculosis, and other pulmonary diseases were excluded from this study. The ethical clearance of this study was obtained by the Biomedical Research Ethics Committee of King Abdulaziz University.

Total IgE level was assessed byUnicap 100 (Pharmacia Diagnostics, Uppsala, Sweden). The assessment of specific IgE was conducted by the ImmunoCAP technology (Phadia Inc., Uppsala, Sweden).A cut off point of 195 IU/ml for IgE level was set to 195 IU/L as used in KAUH immunology laboratory. Twenty specific allergen that were used in ImmunoCAP included Dermatophagoides pteronyssinus (DP), Dermatophagoides farinae (DF), Cockroach, Cat hair, Dog hair, Aspergillus fumigatus, Cladosporium herbarum, Alternaria tenuis, Candida albicans, Salsola kali, Ambrosia, Chenopodium album, Artemisia vulgaris, Plantago lanceolata, Phoenix dactylifera, Prosopis juliflora, Acacia longifolia, Cynodon dactylon, Lolium perenne, Phleum preten in inhalant allergies. Plain tubes were used to collect blood samples for both IgE and ImmunoCAP as says (without anticoagulant). Patients showed concentration of total IgE ≥ 195 IU/ml were considered positives according to the protocol used in KAUH, while in sIgE testing patient showed allergic reaction to one or more allergens was considered positive. In eosinophils percentage assessment, patients with eosinophils

percentage higher than 6% were considered allergic positive patients.

The statistical analysis was conducted using Statistical Package for Social Science (SPSS) version 20. The pooled analysis of all data was done to calculate sensitivity, specificity, and total accuracy, positive and negative predictive values for studied allergy markers in reference to the final clinical diagnosis. The associations between demographic variables and allergy markers with occurrence of the allergic diseases were assessed using chi-square test at alpha significance level of 0.05.

RESULTS

Out of 130 suspected patients, 46.9% were males and 53.1% were females with age ranged from 1 to 77 years old with (Mean ± S.D) of 34±18 years old. Despite 76.9% of study participants were finally diagnosed as allergic patients, only 66.9% showed positive result using sIgE level, and 62.3% were tested positive using total IgE testing. In addition, only 53.8% tested positive using eosinophils percentage.

Table 1: diagnostic accuracy measures for sIgE, total IgE and eosinophils percentage with final diagnosis as gold standard

Investigation	Statistic	Sensitivity	Specificity	Positive Likelihood Ratio	Negative Likelihood Ratio	Positive Predictive Value	Negative Predictive Value
SIgE	**Value**	87.00%	100.00%	-	0.13	100.00%	69.77%
	95% CI	78.80% to 92.89%	88.43% to 100.00%	-	0.08 to 0.22	95.85% to 100.00%	53.87% to 82.82%
Total IgE	**Value**	79.00%	93.33%	11.85	0.22	97.53%	57.14%
	95% CI	69.71% to 86.51%	77.93% to 99.18%	3.09 to 45.38	0.15 to 0.33	91.36% to 99.70%	42.21% to 71.18%
Eosinophils percentage	**Value**	70.00%	100.00%	-	0.3	100.00%	50.00%
	95% CI	60.02% to 78.76%	88.43% to 100.00%	-	0.22 to 0.40	94.87% to 100.00%	36.81% to 63.19%

Table 2: Prevalence of positive ImmunoCAP results and severity class to 20 applied allergens among allergic patients in Jeddah city

Allergens				Severity class of positive Aeroallergens %					
Common name	**Scientific name**	**Number of sIgE**	**Percentage of positive sIgE %**	**I**	**II**	**III**	**IV**	**V**	**VI**
Weeds									
Russian thistle	*Salsola kali*	103	79.2	0.8	7.7	5.4	6.9	0	0
Ragweed	*Ambrosia*	108	83.1	2.3	3.8	4.6	3.8	2.3	0
White goosefoot	*Chenopodium album*	111	85.4	1.5	5.4	6.2	1.5	0	0
Mugwort	*Artemisia vulgaris*	112	86.2	5.4	3.1	1.5	1.5	1.5	0.8
Plantain	*Plantago lanceolata*	119	91.5	2.3	3.1	0.8	1.5	0.8	0
Grasses									
Bermuda grass	*Cynodon dactylon*	112	86.2	1.5	3.8	4.6	2.3	1.5	0
Perennial rye grass	*Lolium perenne*	109	83.8	3.1	3.1	4.6	3.8	1.5	0
Timothy grass	*Phleum pratense*	109	83.8	1.5	4.6	3.8	4.6	0.8	0.8
Trees									
Mesquite	*Prosopis juliflora*	119	91.5	2.3	3.8	2.3	0	0	0
Acacia	*Acacia longifolia*	118	90.8	1.5	2.3	3.8	1.5	0	0
Date palm	*Phoenix dactylifera*	118	90.8	3.8	4.6	0.8	0	0	0
Mites									
House dust mite	*Dermatophagoides farinae*	82	63.1	4.6	8.5	11.5	8.5	0.8	3.1
House dust mite	*Dermatophagoides pteronyssinus*	98	75.4	3.1	5.4	6.2	5.4	3.8	0.8
Molds									
Fungus	*Aspergillus fumigatus*	110	84.6	9.2	5.4	0	0.8	0	0
Fungus	*Cladosporium herbarum*	117	90	0.8	4.6	4.6	0	0	0
Fungus	*Alternaria tenuis*	113	86.9	8.5	3.8	0.8	0	0	0
Fungus	*Candida albicans*	116	89.2	1.5	5.4	2.3	1.5	0	0
Animal									
Cat [hair]	*Feliscatus*	101	77.7	5.4	7.7	6.2	3.1	0	0
Dog [hair]	*Canis familiaris*	108	83.1	1.5	5.4	5.4	3.1	1.5	0
Insects									
American Cockroach	*Periplaneta americana*	96	73.8	4.6	5.4	7.7	6.2	1.5	0.8

The values of (Means±SD) of total IgE were 137±46, 408±406, 980±811, and 800±727 kU/L for normal, asthmatic patients, allergic rhinitis, and allergic dermatitis patients. There was a significant positive correlation between total IgE and eosinophils percentage (r=0.364, P value=0.000)

In regards to the validity measures, the sensitivity and specificity of sIgE testing were found to be 87% and 100% in comparison to 79% and 93% of total IgE respectively. While, the sensitivity and specificity for eosinophils percentage were found 70% and 100% respectively. In addition, positive and negative predictive values of sIgE were found 100% and 69.8% in comparison to 97.5% and 57.1% of total IgE respectively. While positive and negative predictive values of eosinophils percentage were found 100% and 50% respectively (table 1).

DF was the most prevalent allergens among study participants (36.9% of all participants), followed by cockroach, DP, and cat hair with prevalence of 26.2% 24.9%, and 22.3% respectively (table 2).

After clinical and laboratory investigations, 23.1%, 30%, 24.6%, and 22.3% of study participants were finally diagnosed as normal, asthmatics, allergic rhinitis and allergic dermatitis patients respectively. The significant associations were detected between final diagnosis and each of sIgE and total IgE and eosinophil percentage with P values less than 0.001. There was a significant difference between males and females in regards to prevalence of asthma, where 37.7% of females diagnosed as asthmatics in comparison to 21.3% of males. However, in regards to age, there was no significant association with occurrence of allergic diseases (table 3).

Table 3: Significant associations between allergy markers and final clinical diagnosis

The background factor		Diagnosis			
		Asthmatic	Normal	Chi-square	P value
Sex	Male	13 (21.3%)	48 (78.7%)	4.131	0.042
	Female	26 (37.7%)	43 (62.3%)		
		Diagnosis			
sIgE		Allergic	Normal	78.9	0.000
	Positive	87 (100%)	0 (0.0%)		
	Negative	13 (30.2%)	30 (69.8%)		
Total IgE	Positive	79 (97.5%)	2 (2.9%)	58.9	0.000
	Negative	21 (42.9%)	28 (57.1%)		
Eosinophils percentage	Positive	70 (100%)	0 (0.0%)	45.0	0.000
	Negative	30 (50%)	30 (50%)		

DISCUSSION

Proper diagnosis of allergic patients is important for the application of the appropriate management plan. [17] Diagnosis of the allergic diseases does not depend on the laboratory findings alone. Combination of laboratory, familial history, and clinical findings is necessary to obtain a final diagnosis. [18]

In this study, the diagnostic accuracy of important allergic markers such as sIgE, total IgE, and eosinophils percentage was assessed in reference to the final diagnosis. The findings of this study showed that 23.1%, 30%, 24.6%, and 22.3% of study participants were finally diagnosed as normal, asthmatics, allergic rhinitis and allergic dermatitis patients respectively. Despite 76.9% of study participants were diagnosed as allergic patients, only 66.9% showed positive result using sIgE level, and 62.3% were tested positive using total IgE testing. In addition, only 53.8% tested positive using eosinophils percentage. Different results found by Almughales et al. in Saudi Arabia, where they found 74.5% of 1893 study participants showed positive results in total IgE assay with serum level ≥195 kU/L. [12] The present study found that females had significantly higher allergic diseases than males, although the elevation in IgE level is usually associated with young

male smokers. [19] This is in agreement with findings of a study conducted in Anupama et al. [13] who found higher incidence of allergic asthma among females.

In this study, the values of mean±SD of total IgE were 137±46, 408±406, 980±811, and 800±727 kU/L for normal, asthmatic patients, allergic rhinitis, and allergic dermatitis patients. In addition, there was a significant positive correlation between total IgE and eosinophils percentage. Deo et al. found a higher level of IgE among normal Indians with values of mean±SD were 180.96±22.16 IU/ml, which could be attributed to the high incidence of parasitic infections and environmental pollutants in India than in Saudi Arabia. [20] They also found significant correlation between allergic measures such that found between total IgE and eosinophils percentage among allergic rhinitis patients. Almughales et al. found mean of total IgE level among allergic patients and normal population to be 734.7kU/Land 122.1kU/L respectively, which were in agreement with the findings of the present study. [12] A study conducted in 2004,showed that screening for sIgE was not recommended if the total IgE level was less than 10 kU/L, while there was no study participant recorded level less than 10 kU/L in the present study. The cut-off point of IgE level in the present study was slightly higher than previously used cut-off points by western studies, [21,22] because the normal range of IgE tends to be higher in the Middle East populations than that among western populations. [23]

In the present study, the sensitivity and specificity of total IgE were 79% and 93% respectively, while Jung et al. found slightly lower sensitivity of 75.2% and much lower specificity of 69.7%. [24] However, the limited study population used by Jung et al., (patients with allergic rhinitis but without bronchial asthma) could explain these lower values, especially specificity value. The sensitivity and specificity are affected by the prevalence of the disease, thus the prevalence of allergic rhinitis (without bronchial asthma) is much lower than the prevalence of numerous allergic diseases included in the present study. In addition, this disagreement with the findings of Jung et al. could be attributed to the use of a different cut off point (118 IU/ml) of IgE level. The same explanation could be applied to the lower sensitivity and specificity for eosinophils percentage that were 57.5% and 72% [24] in study of Jung et al., in comparison to 70% and 100% that found in the present study. Al-Mughales et al. found the lower values of sensitivity and specificity of total IgE (61.3% and 83.4% respectively) than those found in the present study. However the gold standard test used by Al-Mughales et al. was the sIgE essay not the confirmed final diagnosis as considered by the present study. [12]

Clinically the positive and negative predictive values are more important than sensitivity and specificity because they are not affected by disease prevalence. In this study, the positive and negative predictive values of total IgE were 97.5% and 57.1%. This data provided a good evidence for identifying the clinical importance of total IgE in initial diagnosis of allergic diseases. However, Jung et al. found a lower positive predictive value of 71.3% but a higher negative predictive value of 73.7%, which reflected the fact that positive and negative predictive values are not affected by the disease prevalence. Almughales et al. found different results of positive predictive value and negative predictive value (80.6% and 68.8% respectively), which could be justified by a different gold standard that used to calculate those measures. [12]

In regards to the validity of sIgE, the sensitivity and specificity found to be 87% and 100% in the present study. Paganelli et al. found a similar sensitivity but a slightly lower specificity of 89% and 91% respectively, which were calculated in reference to the clinical diagnosis. [25] This is the same basis used for calculations of all validity measures in the present study.

The present study found the indoor mites allergen DF as the most prevalent allergen among study participants with

prevalence of 36.9%, followed by cockroach, DP, and cat hair with prevalence of 26.2% 24.9%, and 22.3% respectively. Many studies from hot and humid regions reported a high prevalence of mites allergy such as in Singapore [26] and Thailand. [27] Similar conditions are found in Jeddah city with high prevalence of house mites reactivity according to the present study. Mites such as DP and DF prefer a relative humidity ≥ 55%, which is already occur in Jeddah city especially in summer season. The allergic reaction to cockroach allergen found as common as allergy to the house mite allergens in many studies especially among asthmatic patients. [28,29]

This was the first study, which aimed to identify the clinical diagnostic accuracy of different allergy markers at the same time. The limitations of this study included a retrospective approach of data collection, which is more subjected to the random errors and bias. The sample size in the similar studies was used to be larger than the sample size used in the present study. However, this study provided good evidence about the diagnostic accuracy of various allergy markers especially sIgE and total IgE.

CONCLUSION

In conclusion, the clinical sensitivity was very good in sIgE, good in total IgE but fair in eosinophils percentage, while the clinical specificity was excellent in all of these allergy markers. Positive predictive value was excellent in all allergy markers, but negative predictive value ranged from fair value in sIgE to poor value in eosinophils percentage.

Conflict of interest: The authors declare no conflicts of interest.

Funding: No financial support for this study was received.

ACKNOWLEDGEMENT

The author acknowledges and gratefully appreciates the efforts of Dr. Ahmad Aldarmahi for his valuable advice and contributions towards the biostatistical aspects of this research work.

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How to cite this article: Al-Rabia MW. Diagnostic accuracy of sIgE, total IgE and eosinophils percentage among patients with asthma, allergic rhinitis, and atopic dermatitis in Saudi Arabia. Int J Health Sci Res. 2016; 6(10):33-39.

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