Original research

Evaluation of diagnostic accuracy of Allergy Explorer 2 method in children with bronchial asthma and allergic rhinitis in the Kyrgyz Republic

Shairbek A. Sulaimanov, Mukhtar E. Asheraliev, Kalia T. Turatbekova
National Center of Maternity and Childhood Care, Ministry of Health of the Kyrgyz Republic, Bishkek, Kyrgyzstan

Abstract

Objective: The evaluate efficacy and the diagnostic accuracy of Allergy Explorer 2 (ALEX-2) test system in pediatric patients with bronchial asthma (BA) and allergic rhinitis (AR) in conditions of limited access to skin tests in Kyrgyz Republic.

Methods: Overall, 60 children with clinically confirmed BA and/or AR were included in the study. Molecular allergy diagnostics using the ALEX-2 test system was conducted for patients in the study cohort. The methodology included serum analysis to evaluate total IgE levels and detect specific to IgE 295 allergens.

Results: The mean total serum IgE level was 1255.37 (150.43) kUA/L. Boys exhibited significantly higher IgE concentrations compared to girls ($p<0.01$). A high degree of sensitization was identified to pollen allergens, epidermal allergens and domestic common allergens. ALEX-2 test allowed individualizing allergy diagnostics and facilitating precise indications for allergen-specific immunotherapy (ASIT).

Conclusions:. ALEX-2 testing showed high clinical significance in the absence of standard skin tests. Further studies with inclusion of comparative methods of diagnostics are required.

Key words: Diagnostic accuracy, molecular allergology, ALEX-2, children, immunoglobulin E, Kyrgyzstan

(Heart Vessels Transplant 2025; 9: doi: 10.24969/hvt.2025.582)

Highlights

1. The Allergy Explorer-2 test allows detection of dominant sensitizing allergens in children with bronchial asthma and allergic rhinitis.

2. Total immunoglobulin E level has an average serum concentration of 1255.37 (150.43) kUA/L in children with higher levels in boys than in girls.

3. Molecular allergy testing in children with respiratory allergies allows identifying allergens causing pathological reactions with high accuracy.

Introduction

Allergic diseases (AD) are a major health problem. There is a high incidence of allergic diseases worldwide, and the number of severe allergic reactions is increasing; this pathology affects patients of any age category and only progresses over time; significantly deteriorates the quality of life of the patient and his family (1, 2).

In modern conditions, molecular allergy research of patients has become possible, which allows at the molecular level to identify allergens that are causally important in the development of allergic diseases (4, 5). This method also allows to effectively diagnose and carry out cross- and multivalent sensitization prophylaxis in patients (3).

Allergy Explorer-2 (ALEX -2) is a multi-component testing method that allows both the detection of antibodies to both molecular components and allergen extracts in the blood, and provides an almost complete picture of each patient's sensitization.

ALEX is equipped with adapted software that allows analyzing individual allergen panels according to clinical needs –it has multiplex technology (on demand). ALEX-2 is a new generation test for the diagnosis of type 1 allergic reactions (in vitro).

Graphical abstract

Evaluation of diagnostic accuracy of Allergy Explorer 2 method in children with bronchial asthma and allergic rhinitis in the Kyrgyz Republic

Shairbek A. Sulaimanov, Mukhtar E. Asheraliev, Kalia T. Turatbekova, Bishkek, Kyrgyzstan

Sensitization to different allergens in children with allergic diseases by the total IgE level						
	Total 60		Girls (23)		Boys (37)	
Allergens (Ag)	High	Very high	High	Very high	High	Very high
Weed pollen	7	17	4	7	3	10
Pet Ag	7	14	3	7	4	7
Tree pollen	11	8	4	2	7	6
Fruit Ag	5	8	2	1	3	7
Ag mold and yeast fungi	4	8	1	6	3	2
House dust, mites Ag	0	7		2		5
Pet Ag	2	4		2	2	2
Nut and seed Ag	1	4	1	1		3

The results of the study highlight the importance of molecular allergy diagnosis in the detection of individual allergens, which is crucial for developing personalized strategies to treat allergic diseases in children.

Serum concentration of IgE - 1255.37 (150.43) kUA/L in children. Boys had a statistically higher concentration (1331.41 (197.38) kUA/L) than girls (1133.04 (233.78) kUA/L) ($p<0.01$).

Molecular profile of sensitization to pollen allergens in children with BA and AR showed that the highest frequency of sensitization is noted to:
- Perennial ryegrass pollen molecules (Lolium perenne, component Lol p 1) - 18 patients (64,3%),
- Meadow fescue pollen molecules (Phleum pratense, Phl p 1 component) - 18 patients (60%),
- Creeping thistle pollen molecules (Cynodon dactylon, components Cyn d and Cyn d 1) - 15 patients (45.4%),
- Common wormwood pollen molecules (Artemisia vulgaris, component Art v 3) - 10 patients (21,3%).

The ALEX-2 test covers more than 99% of all standard diagnostic tests, detecting 295 species: 178 different allergen molecules and 117 extracts, including a common immunoglobulin E (IgE) level (1, 3, 5).
The aim of the study was to evaluate the spectrum of allergic sensitization in children living in the city of Bishkek and Chuy region suffering from bronchial asthma and allergic rhinitis using modern molecular allergic test ALEX-2.

Methods
Study design and population
The study design is a descriptive observational study, conducted on the basis of the Department of Allergology and Clinical Immunology of the National Center for Maternal and Child Health of the Ministry of Health of the Kyrgyz Republic. The aim of the study was evaluation of diagnostic possibilities ALEX-2 test-system in children with BA and AR. There are no standard skin tests in Kyrgyz Republic, the scarification method is being used, that is not recommended by international guidelines. That is why we did not compare ALEX-2 test results with reference methods.
The study included 60 children with confirmed bronchial asthma (BA) and allergic rhinitis (AR)

diagnosis who sought an outpatient or inpatient care. Patients represented the city of Bishkek (73%) and the Chuy region (27%) of Kyrgyz Republic.
The study protocol was approved by local Ethics Committee of the National Center for Maternal and Child Health. Informed consent to participate in the study was obtained from parent or legal guardians of patients.
Baseline variables
We assessed age and sex of patients, and duration of diseases: BA or AR.
Allergy testing
Patients underwent molecular allergy testing using the ALEX-2 test system (Vendor, Country), which allows for the analysis of sensitization of 295 allergen molecules and allergen extracts, as well as determination of total IgE levels in blood serum. The technique allowed to identify both allergens and individual protein components responsible for the immune response. Positive test results indicated specific sensitization, but the absence of specific IgE did not rule out allergic disease. The data obtained were compared with the historical information.

Statistical analysis
Statistical analysis was performed using XXX software. Data are presented as number, number (percentage), mean and standard deviation. To evaluate differences between groups we used Students t test. Statistical significance was accepted at p<0.05 level.

Results
The age category of children was from 3 to 14 years. Boys predominated among the surveyed (n=37; 61.6%) compared to girls (n=23; 38,3%). The duration of the disease varied from 1 to 7 years.

The serum IgE total was 1255.37 (150.43) kUA/L. IgE concentration was statistically higher in boys (1331.41 (197.38) kUA/L) than in girls (1133.04 (233.78) kUA/L) (p<0.01). The obtained indicators show a high sensitization to various allergens, which confirms the expressed allergic load in the studied cohort.

As shown in Table 1, high sensitization was observed for the allergens of grass pollen in 35% of patients, for the allergens of weeds in 28.3%, for the allergens of domestic animals in 23.3%, and for the allergens of trees in 13.3%.

Table 1. Graded spectrum of sensitization to different groups of allergens in children with allergic diseases by the total immunoglobulin E level

Allergens (Ag)	Total (n=60)					Girls (n=23)					Boys (n=37)				
	Negative	Low	Moderate	High	Very high	Negative	Low	Moderate	High	Very high	Negative	Low	Moderate	High	Very high
Pollen of cereals	23	6	5	**5**	**21**	9	3	1	**2**	**8**	14	3	4	**3**	**13**
Weed pollen	29	2	5	**7**	**17**	10	1	1	**4**	**7**	19	1	4	**3**	**10**
Pet Ag	24	5	10	**7**	**14**	5	3	5	**3**	**7**	19	2	5	**4**	**7**
Tree pollen	28	5	8	**11**	**8**	11		6	**4**	**2**	17	5	2	**7**	**6**
Fruit Ag	31	2	14	**5**	**8**	11	1	8	**2**	**1**	20	1	6	**3**	**7**
Ag mold and yeast fungi	42	2	4	**4**	**8**	12	2	2	**1**	**6**	30		2	**3**	**2**
House dust, mites Ag	51	1	1	**0**	**7**	19	1	1		**2**	32				**5**
Pet Ag	50	1	3	**2**	**4**	20		1		**2**	30	1	2	**2**	**2**
Nut and seed Ag	42	5	8	**1**	**4**	14	1	6	**1**	**1**	28	4	2		**3**

Therefore, the analysis of the concentration of total IgE in blood depending on group affiliation of BA and AR allergies in children showed that the highest and very high levels of IgE in patients with sensitization to pollen of cereals, weeds and allergens of domestic animals. Next in importance was sensitization to allergens of fruits, molds and yeast fungi.

We have given below a spectrum of causally significant allergies in patients using pollen sensitization (Table 2).

The number of patients with very high sensitization in descending order was on molecules of pollen of the long-lived (Lol p 1) at 18 (64.3%), meadow fescue (Phl p 1) at 18 (60%), creeping thistle (Cyn d) at 15 (45.4%), creeping thistle (Cyn d 1) at 15 (45.4%), and wormwood (Art v 3) at 10 (21.3%).

Therefore, the results of molecular allergy testing may have a significant influence on the formation of indications for allergen-specific immunotherapy, increase its effectiveness, allow objectively assessing the risk of anaphylactic reactions and optimize the prognosis and tactics of patients with allergic pathology.

Discussion
Our study demonstrated that use of the Allergy Explorer-2 test system provides a component allergy diagnosis, allowing to identify dominant sensitizing allergens in children with bronchial asthma and allergic rhinitis.

The total IgE level has an average serum concentration of 1 255.37 (150.43) kUA/L in children, being markedly higher in boys than in girls. Our data show a pronounced sensitization to causally significant allergens. Molecular allergy testing in children with respiratory allergies allows to identify allergens causing pathological reactions with high accuracy. In the studied group, sensitization to allergens of pollen was found in 35% of patients, to allergens of pollen of weeds - 28.3%, to epidermal allergens of domestic animals - 23.3%, to allergens of pollen of trees - 13.3%.

Table 2. Spectrum ranking of sensitization to the pollen allergen molecules

Allergen and allergen or extract designation	Total (n=60)					Girls (n=23)					Boys (n=37)				
	Negative	Low	Moderat	High	Very high	Negative	Low	Moderat	High	Very high	Negative	Low	Moderat	High	Very high
Perennial ryegrass (Lol p 1)	28	4	4	6	18	11	2	1	2	7	17	2	3	4	11
Meadow fescue (Phl p 1)	30	4	1	7	18	12	1	4	6		18	3	1	3	12
Creeping thistle (Cyn d)	33	3	5	4	15	12	2	2	1	6	21	1	3	3	9
Creeping thistle(Cyn d 1)	33	3	5	4	15	12	2	2	1	6	21	1	3	3	9
Wormwood (Art v 3)	47		1	2	10	16			2	5	31		1		5
Meadow fescue(Phl p 5.0101)	52	1	0	0	7	19				4	33	1			3
Meadow fescue (Phl p 2)	51	1	0	2	6	21				2	30	1		2	4
Meadow fescue (Phl p 12)	40	4	10	3	3	14	3	6			26	1	4	3	3
Rye,pollen (Sec c_pollen)	45	3	7	2	3	18		3	1	1	27	3	4	1	2
Meadow fescue (Phl p 6)	53	1	3	0	3	19	1	2		1	34		1		2
Annual vetch (Mer a 1)	40	3	7	7	3	14	2	5	2		26	1	2	5	3
Meadow fescue (Phl p 7)	59	0	0	0	1	22				1	37				
Paspalum notatum (Pas n)	43	3	11	3	0	16	1	5	1		27	2	6	2	
Common reed (Phr c)	51	6	3	0	0	19	4				32	2	3		

The study of the molecular profile of sensitization to pollen allergens in children with BA and AP showed that the highest frequency of sensitization is noted to:
- Perennial ryegrass pollen molecules (Lolium perenne, component Lol p 1) - 18 patients (64,3%),
- Meadow fescue pollen molecules (Phleum pratense, Phl p 1 component) - 18 patients (60%),
- Creeping thistle pollen molecules (Cynodon dactylon, components Cyn d and Cyn d 1) - 15 patients (45.4%),
- Common wormwood pollen molecules (Artemisia vulgaris, component Art v 3) - 10 patients (21,3%).

Thus, results of our study demonstrated high efficacy of molecular diagnostic methods ALEX-2 in the conditions of limited availability of skin tests. In Kyrgyzstan the skin test are not used (only scarification test is available), thus reducing possibilities of allergy diagnostics in vivo.

Method ALEX -2 allows identifying specific IgE to 295 allergens and its components, that is important for prescription of i for allergen-specific immunotherapy (ASIT) (1, 3, 5). Comparison of our data with similar study conducted in Europe and Asia (4), confirms high sensitivity of multicomponent diagnostics.

Study limitations

The main limitations of the study is absence of comparison with referent methods sensitivity to allergens, as well as small sample size of patients. Future studies should address inclusion of skin –prick test and use of molecular diagnostics of efficacy of ASIT in dynamics.

Conclusion

The results of the study highlight the importance of molecular allergy diagnosis in the detection of individual allergens, which is crucial for developing personalized strategies to treat allergic diseases in children.

References

1.Namazova-Baranova LS, Nyuszkaya MA, Mityushin IL, Kozhevnikova OV, Batyrova AS. Features of diagnosis of allergy in children. RAMN Bull 2017; 72: 33-41. doi 10.15690/vramn799

2. Sulaimanov SHA, Asheraliev SHA, Muratova JK, Avtandilov AA, Sulaimanov ASH. GINA 2024: key changes and approaches to target therapy. Bull Sci Pract 2024; 10: 259-68. Doi: 10.33619/2414-2948/104/27

3. Dustbabaeva ND, Razykova IS, Baibekova VF. Comparative analysis of the spectrum of sensitization to pollen, food and epidermal allergens in patients with respiratory allergies in Uzbekistan. J Theor Clin Med 2023; 1: 30-5.

4. Jensen-Jarolim E, Jensen AN, Canonica GW. Debates in allergy medicine: molecular allergy diagnosis with ISAC will replace screenings by skin prick test in the future. /World Allergy Org J 2017; 10: 1-6.

5. Bernstein IL, Li JT, Bernstein DI. Allergy diagnostic testing: An updated practice parameter. Ann Allergy Asthma Immunol 2008; 100 (3 Suppl 3): S1-S148.