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Comparison and clinical utility evaluation of four multiple allergen simultaneous tests including two newly introduced fully automated analyzers

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ABSTRACT

Background: We compared the diagnostic performances of two newly introduced fully automated multiple allergen simultaneous tests (MAST) analyzers with two conventional MAST assays.

Methods: The serum samples from a total of 53 and 104 patients were tested for food panels and inhalant panels, respectively, in four analyzers including AdvanSure AlloScreen (LG Life Science, Korea), AdvanSure Allostation Smart II (LG Life Science), PROTIA Allergy-Q (ProteomeTech, Korea), and RIDA Allergy Screen (R-Biopharm, Germany). We compared not only the total agreement percentages but also positive propensities among four analyzers.

Results: Evaluation of AdvanSure Allostation Smart II as upgraded version of AdvanSure AlloScreen revealed good concordance with total agreement percentages of 93.0% and 92.2% in food and inhalant panel, respectively. Comparisons of AdvanSure Allostation Smart II or PROTIA Allergy-Q with RIDA Allergy Screen also showed good concordance performance with positive propensities of two new analyzers for common allergens (*Dermatophagoides farina* and *Dermatophagoides pteronyssinus*). The changes of cut-off level resulted in various total agreement percentage fluctuations among allergens by different analyzers, although current cut-off level of class 2 appeared to be generally suitable.

Conclusions: AdvanSure Allostation Smart II and PROTIA Allergy-Q presented favorable agreement performances with RIDA Allergy Screen, although positive propensities were noticed in common allergens.

1. Introduction

The detection of allergen-specific IgE, along with the patient's chief complaints and medical history, is diagnostically valuable for allergic diseases, such as allergic rhinitis, atopic dermatitis, and asthma [1,2]. Although in vivo skin test has been traditionally used in the clinical environments, there are several limitations of in vivo skin test including error-prone results

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in patients with anti-histamine medication or skin diseases such as dermographism, possibility of subjective interpretation, and the lack of standardization for protocols [3,4]. Therefore, in vitro allergen-specific IgE measurements have been developed using various principles of radioimmunoassay, enzyme immunoassay, fluorescent enzyme immunoassay, immunoblot, and chemiluminescent assay [5–7].

Among the commercially available in vitro allergy tests, multiple allergen simultaneous tests (MAST) have been continuously developed with the improvements in smaller amounts of serum consumption, shorter turnaround time, and wider spectrum of allergens included in the test [6,8–12]. Since the difference in prevalence of allergic diseases according to age, sex, and ethnicity is prominent, the selection of multiple allergen screening panels should be modified in the context of geographical regions and race of the target populations [13–15]. At the same time, the change of environmental substances in modern society must be considered for the progressive development of MAST assays [16].

Moreover, there is no appropriate medical evidence to define any assay as the standardized reference method due to variability of allergen original materials, extraction methods, attachment processes, and detection techniques [5]. Therefore, it is very difficult to analyze true sensitivity, specificity, positive predictive value, and negative predictive value of a specific MAST assay. Nevertheless, actual comparison of new MAST assay with currently used MAST assays can appropriately provide important information in the practical clinical settings.

Recently, two fully automated analyzers with high-throughput were developed and introduced in the market; AdvanSure Allostation Smart II which is the upgraded version of previous AdvanSure AlloScreen by LG Life Science, and PROTIA Allergy-Q which was newly developed by ProteomeTech. Herein, we compared the diagnostic performances of these assays with two most commonly used MAST assays in Korea, today. In addition, we evaluated propensity of each assay to give positive results for certain allergen, which we defined as “positive propensity”.

2. Methods

2.1. Study participants

We randomly selected the study samples from MAST assay requested serum samples of patients who visited Severance Hospital with symptoms of allergy including urticaria, sneezing, and itching for diagnosis of allergic disease in all age ranges. Additionally, we excluded patients with chronic comorbid diseases such as autoimmunity, malignancy, chronic infection, and other immune-related diseases. Since two different panels were evaluated, we classified patients into two groups so that appropriate panel could be tested based on clinical symptoms and medical records. Due to the variety of allergen types included in the panel of four assays and lack of sufficient sample volume in some patients, different samples were analyzed by different numbers of analyzers with various combinations of allergens. Therefore, only pairs of matched allergens by the same sample were compared among four analyzers.

2.2. In vitro allergen-specific IgE measurements

Serum aliquots were tested by four different systems; AdvanSure AlloScreen (LG Life Science, Seoul, Korea), AdvanSure Allostation Smart II (LG Life Science, Seoul, Korea), PROTIA Allergy-Q (ProteomeTech, Seoul, Korea), and RIDA Allergy Screen (R-Biopharm, Darmstadt, Germany). All the test procedures were performed following the manufacture’s instruction. Although detection ranges were various among four analyzers, results were identically classified into 7 levels and were interpreted as class 0–6 in all analyzers (Table 1).

Table 1
Specifications of four different MAST analyzers.

	AdvanSure AlloScreen	AdvanSure Allostation Smart II	PROTIA Allergy-Q	RIDA Allergy Screen
Manufacturer	LG Life Science (Korea)	LG Life Science (Korea)	ProteomeTech (Korea)	R-Biopharm (Germany)
Instrument	AdvanSure™ Allostation	AdvanSure™ Allostation Smart II	Q-station	AlleRoboT
Reagent	AdvanSure™ Alloscreen	AdvanSure™ Alloscreen	PROTIA™ Allergy-Q	AlleisaScreen®
Principle	Immunoblot	Immunoblot	Immunoblot	Immunoblot
Class stratification	Class 0–6	Class 0–6	Class 0–6	Class 0–6
Degree of automation	Semi automation	Full automation	Full automation	Full automation
Number of antigens				
-Total (common)	60 (20)	90 (30)	70 (18)	80 (40)
-Food panel	40	60	44	60
-Inhalant panel	40	60	44	60
Minimal sample volume (μl)	100	250	120	800
Tested sample volume (μl)	100	100	50	300
Number of strips utilized	2	2	1	2
Capacity or number of tests per run	24	30	48	36
Analysis time (hr)	3.5	4.0	4.0	3.8
Analysis time per sample (min)	8.75	8	5	6.3