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EVALUATION OF THE EFFECTIVENESS OF MOLECULAR ALLERGY DIAGNOSTIC METHODS IN THE PERSONALIZED MANAGEMENT OF PATIENTS WITH ALLERGIC RHINITIS

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Abstract

Introduction: Allergic rhinitis (AR) is a common IgE-mediated condition that significantly reduces quality of life. Conventional diagnostic methods do not always allow for the accurate identification of causative allergens, especially in cases of polysensitization.

Objective: A comparative evaluation of the effectiveness of two molecular allergy diagnostic methods—ImmunoCAP and immunochemiluminescent assay (ICLA)—in patients with allergic rhinitis.

Methods: A retrospective study involving 60 patients with confirmed AR was conducted. Sensitivity, specificity, predictive values, and overall diagnostic performance of the methods were analyzed. Pearson's chi-squared test, ROC analysis, and calculation of AUC were applied.

Results: ImmunoCAP demonstrated a sensitivity of 87.8% and an AUC of 0.88. ICLA showed higher specificity (61.3%) and an AUC of 0.79. PPV was comparable (66.7% vs. 65.7%), whereas NPV was higher for ICLA (76.0% vs. 16.7%). The differences between the methods were statistically significant (p = 0.001).

Conclusions: Both methods are valuable tools in the diagnosis of AR. ImmunoCAP is preferable for the initial detection of sensitization, while ICLA is more suitable for confirming clinically relevant allergy and minimizing false-positive results.

Keywords: *Allergic rhinitis, IgE, allergy diagnostics, ICLA, ImmunoCAP, personalized medicine.*

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Резюме

ОЦЕНКА ЭФФЕКТИВНОСТИ МЕТОДОВ МОЛЕКУЛЯРНОЙ АЛЛЕРГОДИАГНОСТИКИ В ПЕРСОНАЛИЗИРОВАННОМ ВЕДЕНИИ ПАЦИЕНТОВ С АЛЛЕРГИЧЕСКИМ РИНИТОМ

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Введение: Аллергический ринит (АР) — распространённое IgE-опосредованное заболевание, существенно снижающее качество жизни. Традиционные методы диагностики не всегда позволяют точно определить причинно-значимые аллергены, особенно при полисенсибилизации.

Цель: Сравнительная оценка эффективности молекулярных методов диагностики аллергии ImmunoCAP и иммунохемилюминесцентного анализа (ИХЛА) у пациентов с аллергическим ринитом.

Методы: Ретроспективное исследование с участием 60 пациентов с подтверждённым АР. Проанализированы чувствительность, специфичность, прогностические значения и диагностическая эффективность методов. Применялись χ^2-критерий, ROC-анализ и расчёт AUC.

Результаты: Чувствительность ImmunoCAP составила 87,8%, AUC – 0,88. ИХЛА показал большую специфичность (61,3%) и AUC – 0,79. PPV был сопоставимым (66,7% vs. 65,7%), тогда как NPV выше у ИХЛА (76,0% vs. 16,7%). Различия между методами статистически значимы (p = 0,001).

Выводы: Оба метода являются ценными инструментами диагностики АР. ImmunoCAP предпочтителен при первичном выявлении сенсибилизации, ИХЛА — для подтверждения клинически значимой аллергии и снижения количества ложноположительных результатов.

Ключевые слова: *Аллергический ринит, IgE, аллергологическая диагностика, ИХЛА, ImmunoCAP, персонализированная медицина.*

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Түйіндеме

АЛЛЕРГИЯЛЫҚ РИНИТІ БАР НАУҚАСТАРДЫ ЖЕКЕ БАСҚАРУДАҒЫ МОЛЕКУЛАЛЫҚ ДИАГНОСТИКАЛЫҚ ӘДІСТЕРДІҢ ТИІМДІЛІГІН БАҒАЛАУ

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Кіріспе: Аллергиялық ринит – IgE-делдалды созылмалы қабыну ауруы. Көп жағдайда дәстүрлі диагностикалық әдістер себепші аллергенді дәл анықтауға мүмкіндік бермейді.

Зерттеу мақсаты: Аллергиялық ринитпен ауыратын науқастарда ImmunoCAP және иммунды-хемилюминесценттік талдау (ИХЛА) әдістерінің диагностикалық тиімділігін салыстырып бағалау.

Зерттеу әдістері: Алматы қаласындағы клиникада 60 науқасқа ретроспективті зерттеу жүргізілді. ROC-анализ, χ^2-сынамасы, AUC, диагностикалық көрсеткіштер есептелді.

Нәтижелері: ImmunoCAP сезімталдығы – 87,8%, AUC – 0,88. ИХЛА спецификалығы – 61,3%, AUC – 0,79. PPV салыстырмалы (66,7% пен 65,7%), ал NPV ИХЛА-да жоғары (76,0% пен 16,7%). Айырмашылықтар статистикалық тұрғыдан маңызды (p = 0,001).

Қорытынды: Екі әдіс те аллергиялық ринитті диагностикалауда құнды. ImmunoCAP бастапқы скринингке лайық, ал ИХЛА нақты сенсибилизацияны растау үшін тиімді.

Түйінді сөздер: *Аллергиялық ринит, IgE, аллергия диагностикасы, ИХЛА, ImmunoCAP, жекешелендірілген медицина.*

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Introduction

Allergic rhinitis (AR) is a chronic inflammatory disorder of the nasal mucosa caused by an IgE-mediated response to inhaled allergens. Globally, the prevalence of AR reaches 25–30% and continues to rise, especially under conditions of urbanization and environmental degradation [1]. AR significantly reduces patients' quality of life, is associated with sleep disturbances, decreased work productivity, and may serve as a predictor for the development of bronchial asthma and other respiratory diseases [2].

Conventional diagnostic approaches include clinical history, physical examination, skin prick testing, and total IgE assessment. However, these methods do not always allow for the accurate identification of causative allergens or

the sensitization profile. The relevance of more precise diagnostic tools increases, particularly in cases of polysensitization or cross-reactivity [3].

The development of molecular allergy diagnostics based on the detection of allergen-specific IgE to individual molecular components has enabled the implementation of personalized management strategies in patients with AR. Specifically, ImmunoCAP (a fluorescence immunoassay) and immunochemiluminescent assay (ICLA) are among the main technologies used for the quantitative measurement of specific IgE [4]. The personalized molecular approach in allergology allows for the precise identification of clinically relevant sensitizations and optimization of allergen-specific immunotherapy (AIT), reducing the risk of treatment inefficacy [5]. These technologies represent a paradigm shift from empirical approaches to precision diagnostics in allergology.

Currently, ImmunoCAP is more widely recognized as the “gold standard” in molecular diagnostics, whereas ICLA is increasingly utilized in clinical practice due to its availability, automation, and high reproducibility. However, there is a lack of studies comparing the performance of these methods in real-world clinical settings for the diagnosis of AR [6]. Therefore, the comparative effectiveness of ImmunoCAP and ICLA remains a matter of debate [7],[8]. Some studies suggest that ImmunoCAP may overestimate the clinical relevance of sensitization, while ICLA may be more suitable for confirming AR diagnosis [9],[10].

The aim of this study was to evaluate the diagnostic effectiveness of two molecular allergy diagnostic methods - ImmunoCAP and immunochemiluminescent assay (ICLA) - in the personalized management of patients with allergic rhinitis and to perform a comparative analysis.

Research objectives: to determine the sensitivity, specificity, and predictive values of molecular allergy diagnostics using ImmunoCAP and ICLA in patients with allergic rhinitis;

Materials and Methods

A retrospective descriptive study was conducted in an outpatient setting at the *Prima Medical Group* clinic (Almaty, Kazakhstan) from October 2023 to September 2024. The study analyzed outpatient records of patients referred for molecular allergy diagnostics using ImmunoCAP and immunochemiluminescent assay (ICLA) for the evaluation of diagnostic performance. A total of 60 patient records were selected, with patient ages ranging from 18 to 60 years, all meeting international ARIA criteria for the diagnosis of allergic rhinitis. The study population was formed using a continuous sampling method and included patients with a confirmed diagnosis of AR who sought medical care between 2022 and 2023.

Inclusion criteria were: age ≥18 years, confirmed sensitization based on patient history, skin testing and/or the presence of allergen-specific IgE (sIgE) antibodies, and availability of both ImmunoCAP and ICLA test results.

Exclusion criteria included decompensated chronic or autoimmune diseases and uncontrolled comorbid bronchial asthma. All patients were instructed to discontinue antihistamines at least 5–7 days prior to testing to minimize interference with the results. Blood samples were collected in the morning hours following a light fasting period to reduce variability in IgE levels. Both assays were performed in accordance with the manufacturers’ protocols and internal laboratory quality standards.

Seven inhalant allergen extracts were used for testing: birch, ragweed, house dust mite (*Dermatophagoides pteronyssinus*), mold (*Alternaria alternata*), cat epithelium, timothy grass, and mugwort. The ImmunoCAP method was performed using the Phadia 250 analyzer (Thermo Fisher Scientific), while ICLA testing was performed using the Immulite 2000 analyzer (Siemens). The measurement range for both methods was 0.1–100 kU/L, with a cutoff value of 0.35 kU/L.

Data were processed using IBM SPSS Statistics software. Descriptive statistics were used (mean (M), standard deviation (SD), median (Me), mode (Mo)), along with Pearson’s χ^2 test and ROC analysis. The significance threshold was set at $p < 0.05$. Confidence intervals (95% CI) were reported. The following diagnostic metrics were calculated: sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and likelihood ratios.

Ethical Considerations

The study was conducted in accordance with ethical standards and the principles of the Declaration of Helsinki. The study was approved by the local Ethics Committee of Kazakhstan Medical University “KSPH” (Protocol No. 18/23, dated September 25, 2023). No personal identifying information was disclosed.

Results

The study included 60 patients diagnosed with allergic rhinitis, of whom 36 (60.0%) were women and 24 (40.0%) were men. The mean age of the patients was 35.0 ± 11.2 years (95% CI: 32.1–37.9).

Table 1.

General demographic characteristics of the sample.

Parameter	Value
Number of patients	60
Female, n (%)	36 (60,0 %)
Male, n (%)	24 (40,0 %)
Mean age, n (%)	35.0 ± 11.2 (95 % ДИ: 32.1–37.9)

The diagnostic performance of the ImmunoCAP and ICLA methods was assessed using the following indicators: sensitivity, specificity, positive and negative predictive values, and overall diagnostic efficiency.

Table 2.

Comparative diagnostic performance of the methods.

Indicator	ImmunoCAP	ICLA
True positives (TP), n	36	23
False positives (FP), n	18	12
False negatives (FN), n	5	6
True negatives (TN), n	1	19
Sensitivity (%)	87.8	79.3
Specificity (%)	51.3	61.3
Positive predictive value (%)	66.7	65.7
Negative predictive value (%)	16.7	76.0
Diagnostic efficiency (%)	61.7	70.0

The mean level of specific IgE measured by ImmunoCAP was 40.3 ± 9.8 kU/L (95% CI: 38.1–42.5) (Figure 1).

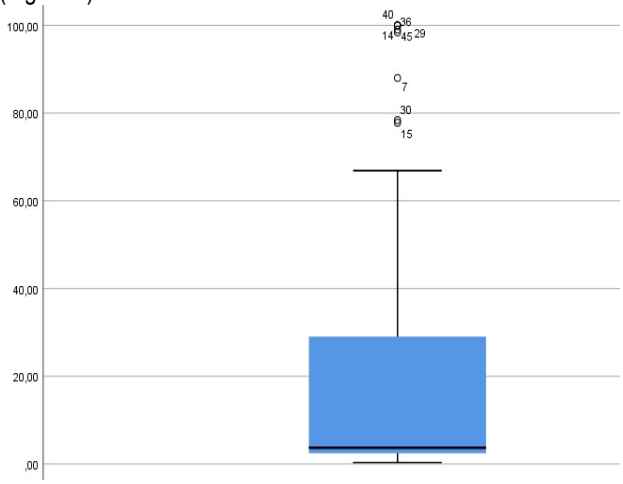

Figure 1. Distribution of specific IgE levels using the ImmunoCAP method.

The mean level of specific IgE by ICLA was 36.0 ± 10.4 kU/L (95% CI: 33.7–38.3) (see figure 2).

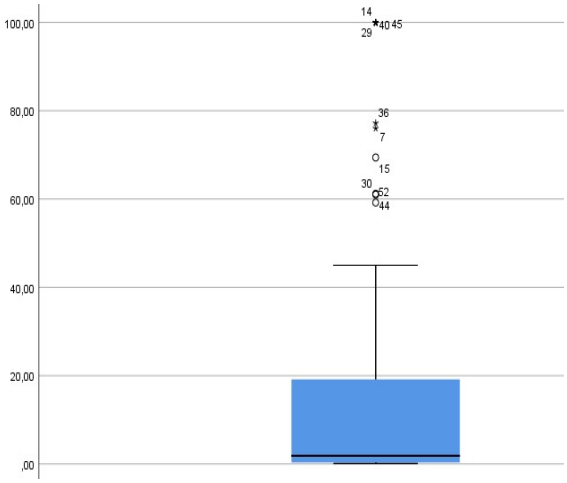

Figure 2. Distribution of specific IgE levels using the ICLA method.

The area under the ROC curve (AUC) was 0.88 for ImmunoCAP and 0.79 for ICLA, indicating high and good diagnostic accuracy, respectively (see figure 3). The difference was statistically significant based on Pearson's χ^2 test ($\chi^2 = 12.4$; df = 1; p = 0.001). Both methods showed acceptable diagnostic utility for allergic rhinitis. ImmunoCAP demonstrated higher sensitivity, while ICLA had greater specificity. The advantage of ICLA was its higher diagnostic efficiency and a lower number of false-positive results.

Sensitivity and specificity values were further stratified by individual allergens, revealing that ImmunoCAP showed the highest sensitivity for house dust mite and birch pollen, whereas ICLA demonstrated superior specificity for mugwort and cat epithelium allergens. This suggests a possible allergen-dependent performance profile.

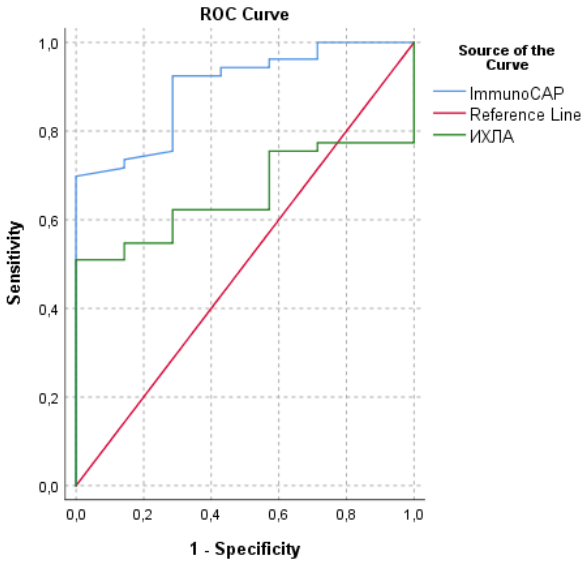

Figure 3. Comparison of method sensitivity and specificity (ROC curves).

Discussion

Allergic rhinitis is characterized by the progressive nature of the pathological process, including the risk of complications and development of more severe disease forms such as bronchial asthma [11]. Patients with allergic rhinitis often experience cognitive impairments, sleep disturbances, daytime fatigue, irritability, and depressive symptoms, all of which substantially reduce quality of life and interfere with daily functioning [12].

Prick tests and skin allergy testing are traditionally used for diagnosing AR. However, the results of skin tests may be unreliable due to multiple factors, leading to false-positive or false-negative outcomes [13]. This necessitates the application of more precise laboratory methods to objectively confirm allergic sensitization—namely, molecular allergy diagnostics [14]. Thus, in this study we compared two modern molecular diagnostic methods—ImmunoCAP and immunochemiluminescent assay (ICLA)—to assess their diagnostic effectiveness in managing patients with allergic rhinitis.

Comparison of Sensitivity and Specificity

The results of this study showed that ImmunoCAP had higher sensitivity (87.8%), whereas ICLA demonstrated greater specificity (61.3%). These findings align with data from Korean researchers, where ImmunoCAP also exhibited superior sensitivity compared to other methods for specific IgE detection [7]. At the same time, recent data suggest that the innovative NOVEOS method using chemiluminescence provides high specificity (96.2%) and may serve as a reliable tool for diagnosing AR, offering comparable results to ImmunoCAP with a significantly smaller sample volume [15].

According to our data, the high sensitivity of ImmunoCAP was associated with an increased number of false-positive results (18 cases), which could lead to overdiagnosis of sensitization. In contrast, the higher specificity of ICLA helped reduce false positives, though it slightly increased the likelihood of false-negative results (6 cases). The choice of diagnostic method should be guided by the clinical context: ImmunoCAP is preferable in cases of polysensitization, while ICLA is more appropriate for confirming clinically relevant allergy [5].

It is important to note that differences in sensitivity and specificity may be due to the technical characteristics of the

assays: fluorescence-based detection (ImmunoCAP) yields stable signals measurable with high sensitivity, but lower concentrations of IgE can lead to higher background noise. Meanwhile, chemiluminescent reactions generate strong signals even at low IgE concentrations, providing more accurate detection in such cases [16].

Predictive Value of the Tests

An important measure of a diagnostic method's effectiveness is its **positive predictive value (PPV)** and **negative predictive value (NPV)**. In our study, the PPV for ImmunoCAP was 66.7%, and for ICLA it was 65.7%, indicating similar capabilities of both methods in predicting the presence of sensitization. However, the NPV was significantly higher for ICLA (76.0% vs. 16.7% for ImmunoCAP), highlighting its advantage in ruling out allergic rhinitis. These findings are consistent with those of a German study, in which ImmunoCAP also demonstrated a higher PPV but was inferior to alternative methods in terms of NPV [17].

ROC Curve Analysis

The diagnostic accuracy of the methods was evaluated using ROC analysis. The **area under the ROC curve (AUC)** for ImmunoCAP was 0.88, indicating high predictive capability. Meanwhile, the AUC for ICLA was 0.79, also reflecting good diagnostic accuracy and the method's utility in differential diagnosis [18]. The differences between the methods were statistically significant ($p = 0.001$), underscoring the importance of choosing the appropriate method based on the clinical context. These results are consistent with prior studies showing higher AUC values for ImmunoCAP compared to other diagnostic tools for allergic rhinitis [19].

Clinical Applications of the Methods

Several studies suggest that combining both methods may enhance diagnostic precision, especially in patients with polysensitization. It is recommended to use ImmunoCAP for initial screening, and ICLA for confirmatory diagnostics [20],[21]. However, given its relatively high sensitivity, ImmunoCAP can be considered a suitable method for primary testing in AR patients with complex clinical presentations or inconclusive skin test results. On the other hand, ICLA—with its higher specificity and strong NPV—is preferable for confirming allergen sensitization. Accordingly, molecular allergy diagnostics should be selected based on individual patient characteristics [3].

Both single-component molecular diagnostic methods have clear clinical value. The choice between them should depend on the diagnostic objective and the need for a personalized approach in managing allergic rhinitis.

Our study has several limitations. First, the retrospective design limits the ability to establish causal relationships between molecular diagnostic results and clinical manifestations of allergic rhinitis. Second, the relatively small sample size and single-center nature of the study restrict the generalizability of the findings. Moreover, the use of a limited allergen panel may not fully reflect the spectrum of sensitization, and the lack of comparison with other diagnostic methods also constrains interpretation. These factors highlight further multicenter prospective studies are warranted to validate the diagnostic accuracy of ImmunoCAP and ICLA in diverse patient populations. Integration of molecular diagnostics with emerging biomarkers and digital health tools may enhance personalized allergy management. Additionally, long-term studies assessing the predictive value of these methods for treatment response and disease progression are needed. Moreover, as the burden of allergic diseases continues to grow globally, incorporating precise diagnostic tools such as ImmunoCAP and ICLA into national clinical guidelines could improve early detection and targeted interventions. These methods may also play a role in public health surveillance by identifying regional sensitization patterns and guiding preventive strategies in high-risk populations.

Conclusion

This study demonstrated that the ImmunoCAP method has higher sensitivity (87.8%) in detecting sensitization in patients with allergic rhinitis, making it particularly effective in complex diagnostic cases. The immunochemiluminescent assay (ICLA) showed greater specificity (61.3%) and a higher negative predictive value (76.0%), confirming its utility in verifying AR diagnosis and minimizing false-positive results. ROC curve analysis revealed statistically significant differences between the two methods ($p = 0.001$), with ImmunoCAP showing superior diagnostic accuracy (AUC = 0.88) compared to ICLA (AUC = 0.79). Both methods are valuable tools in the diagnosis of allergic rhinitis; however, their application should be justified by clinical context: ImmunoCAP is suitable for screening, while ICLA is preferable for confirmation and reduction of overdiagnosis.

Further studies are needed to investigate the prognostic value of molecular allergy diagnostics in long-term patient monitoring, as well as their effectiveness in personalized allergen-specific immunotherapy planning.

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***Conflict of Interest:** The authors declare no conflicts of interest. This material has not been submitted to other journals and is not under consideration elsewhere.*

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