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# CLINICAL AND IMMUNOLOGICAL FEATURES OF OMALIZUMAB TREATMENT OF ATOPIC BRONCHIAL ASTHMA IN UZBEKISTAN

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**Abstract**

**The aim of the study** was to study the effect of Omalizumab on clinical and im-munological parameters in patients with atopic bronchial asthma in Uzbekistan.

**Materials and methods.** 36 patients with atopic bronchial asthma who were administered Omalizumab at a dose of 150 mg (Novartis, Norway) were examined. Before and after treatment, patients underwent a general blood test, total IgE and immune status, including determination of the level of lymphocytes, CD3, CD4, CD8, CD16, CD20, CD23, CD25, CD95 subpopulations.

**Results**. During treatment with Omalizumab for atopic asthma, there was a tendency to decrease ESR, relative eosinophil count, significant decrease in leuko-cyte count, absolute eosinophil count, significant decrease in absolute CD8, CD16, and CD23 counts, and an increase in total IgE.

**Conclusions**:

1. The use of Omalizumab in patients with atopic asthma leads to a decrease in the content of eosinophils and leukocytes.
2. Omalizumab reduces CD8, CD16, and CD23 levels in atopic asthma.
3. A single application of Omalizumab leads to an increase in the level of total IgE in patients with atopic asthma with clinical improvement.

**Keywords**: Atopic bronchial asthma, Omalizumab, immune status.

## Introduction

Despite the fact that the effect of Omalizumab on IgE in the atopic form of bronchial asthma (BA) is well known and has been studied for a long time, the effect on cellular immunity has not been sufficiently studied. It is traditionally believed that the IgE antagonist Omalizumab does not affect the indicators of cellular immunity [6]. However, atopic asthma is an immune-dependent disease and, therefore, is characterized by changes in cellular immunity, which has been studied for a long time. It is known that the immune response includes cellular and humoral cooperation of the immune response. Naturally, the blockade of any link, including the humoral one, will be accompanied by certain changes in the immune response in atopic asthma [2, 3, 7]. It is a well-known fact that there



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are regional differences in the immune response in asthma, both in the disease itself and in the response to treatment, depending on climatic and geographical conditions.

**The purpose of our study** was to study the effect of Omalizumab on clinical and immunological parameters in patients with atopic bronchial asthma in Uzbekistan.

**Materials and methods**

36 patients with atopic asthma were examined, 21 of them were women. The average age was 32.44±3.65 years, the average duration of the disease was 8.16±3.26 years. The diagnosis of atopic asthma was established according to the GINA classification (2023) after a clinical and instrumental examination. Previously, these patients received various inhalers and retrosternal hormone therapy. Omalizumab (Xolar) at a dose of 150 mg (Novartis, Norway) was administered subcutaneously after a complete clinical and immunological examination. All patients underwent a general blood test before and after treatment, and their immune status was examined, including determination of the level of lymphocytes, CD3, CD4, CD8, CD16, CD20, CD23, CD25, CD95, and total Ig E subpopulations. The phenotype of lymphocytes - CD3, CD4, CD8, CD16, CD20, CD23, CD25, CD95 was studied by the method of monoclonal antibodies. The Ig E level was determined by the ELISA method according to the manufacturer's instructions. A general blood test was performed on a hematology analyzer using a set of supplied reagents. A re-examination of the total blood count and immunological para meters was carried out 4 weeks after the administration of Xolar. The control group consisted of 20 healthy individuals of comparable age and gender.

Statistical processing of the obtained results was performed using the Statistica 12.0 software package. The values were considered reliable at $p<0.05$.

**Results and Discussion**

We studied the effect of Omalizumab on the level of a number of indicators of a general blood test. The results are shown in table 1.

Table 1 The effect of Omalizumab on certain blood parameters in patients with allergic asthma

| № | Indicators | Before treatment | After treatment | Healthy |
|---|---|---|---|---|
| 1 | Eosinophils, $10^6$/l | 0,51±0,10□ | 0,45±0,09*,** | 0,21±0,01 |
| 2 | Basophila, | 0,03±0,003□ | 0,03±0,001** | 0,01±0,001 |
| 3 | Eosinophil,% | 6,54±1,32□ | 5,94±1,15** | 0,9±0,01 |
| 4 | Basophila,% | 0,40±0,05□ | 0,4±0,1** | 0,1±0,01 |
| 5 | Neutrophil,$10^6$/l | 5,10±0,51 | 4,02±0,30 | 4,12±0,03 |
| 6 | Lymphocytes,$10^6$/l | 2,53±0,17 | 2,54±0,18 | 2,04±0,15 |
| 7 | Monocyte,$10^6$/l | 0,52±0,03 | 0,45±0,03 | 0,44±0,12 |
| 8 | Neutrophil,% | 56,15±2,35 | 53,28±2,01 | 54,12±1,83 |
| 9 | Lymphocytes,% | 30,94±1,85 | 34,29±1,99** | 30,1±1,1 |
| 10 | Monocyte, % | 6,2±0,29 | 6,08±0,26 | 5,85±0,78 |
| 11 | ESR, mm/h | 14,51±2,33 | 10,20±2,03 | 11,13±3,08 |
| 12 | leukocytes, $10^6$/l | 8,65±0,53□ | 7,49±0,40** | 6,79±0,16 |

Note: * - the reliability between the indicators before and after treatment; ** - the reliability between the indicators after treatment and healthy; □ - reliability between pre - treatment and healthy indicators



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The data in Table 1 indicate a downward trend in ESR, the relative index of eosinophils and neutrophils, a significant decrease in the level of leukocytes, the absolute index of eosinophils and an increase in the absolute index of lymphocytes. The results indicate a significant increase in the relative and absolute values of eosinophils and basophils in comparison with healthy individuals, however, a single administration of Omalizumab leads to a significant decrease in the absolute value of eosinophils ($p<0.05$). It is known that only with the course application of the drug the normalization of the content of eosinophils occurs. The increase in lymphocyte count after Omalizumab has a redistributive character. It should also be noted that the degree of increase in eosinophils and basophils in atopic asthma may depend on local climatic and geographical conditions and the degree of environmental pollution. Omalizumab reduces the number and activity of eosinophils in patients with atopic bronchial asthma, which is manifested in a decrease in their penetration into the bronchi and sputum. It does this by blocking the binding of IgE to inflammatory cells, which, in turn, reduces the expression of IgE receptors, leads to apoptosis (death) of eosinophils and reduces their infiltration into the respiratory tract. eliminates IgE from the blood stream without causing mast cell degranulation [10]. The drug does not directly affect basophils, but a decrease in the level of circulating IgE is accompanied by a decrease in the number of FceRI receptors on the surface of basophils, which potentiates the effect of Omalizumab, since it reduces the susceptibility of mast cells to degranulation. Omalizumab does not directly affect all factors affecting ESR, but only a specific mediator of allergy, it does not directly change ESR, but with a decrease in the overall degree of inflammation in the body associated with an allergic reaction, ESR may decrease indirectly [11, 15, 20].

Table 2 shows the results of immunological changes during treatment with Xolar (Omalizumab).

Table 2 Dynamics of immunological parameters during Omalizumab treatment in patients with atopic asthma.

| № | Indicators | Patients (n=36) | | Healthy (n=20) |
|---|---|---|---|---|
| | | Before treatment | After treatment | |
| 1 | leukocytes, $10^6$/l | 5412,12±345,17 | 4923,07±392,72 | 6787,75±161,7 |
| 2 | Lymphocytes, % | 30,33±1,12 | 29,61±1,97 | 30,1±1,1 |
| 3 | Lymphocytes | 1616,85±103,53 | 1439,38±145,69 | 2043±147 |
| 4 | CD3,% | 44,06±2,01* | 43,15±3,67* | 57,5±1,6 |
| 5 | CD3 | 706,42±59,92* | 621,92±84,43* | 1189±89 |
| 6 | CD4,% | 24,57±1,97* | 24,69±3,26* | 36,2±1,03 |
| 7 | CD4 | 375,06±33,73* | 345,69±53,09* | 752±61 |
| 8 | CD8,% | 18,61±1,41* | 15,86±1,41* | 22,4±1,2 |
| 9 | CD8 | 281,24±24,28* | 219,77±23,58*,** | 475±42 |
| 10 | CD4/CD8 | 1,43±0,09 | 1,58±0,13 | 1,56±0,01 |
| 11 | CD16,% | 14,36±1,06* | 13,38±0,93 | 11,9±0,8 |
| 12 | CD16 | 223,76±22,23 | 186,69±18,16*,** | 286±27 |
| 13 | CD20,% | 19,06±0,92 | 18,46±1,24 | 22,3±0,6 |
| 14 | CD20 | 294,88±22,16* | 260,84±28,59* | 449±37 |
| 15 | CD23,% | 14,45±0,71 | 10,53±0,82*,** | 16,83±0,43 |
| 16 | CD25,% | 14,88±1,15* | 13,84±1,43* | 20,1±0,7 |
| 17 | CD95,% | 14,45±0,65* | 14,35±1,24* | 28,0±1,1 |
| 18 | Total IgE, mg/l | 574,91±113,98* | 1169,79±272,20*,** | 19,51±1,7 |



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Note: *- confidence between the indicators and healthy individuals ($p<0.05$), **- confidence between the indicators before and after treatment ($p<0.05$).

It was previously revealed that Omalizumab affects T cells in bronchial asthma by reducing the number of certain subtypes of T cells and associated inflammatory cytokines, altering the cellular cooperation of the immune response. It is known that the atopic form of asthma is an immune-dependent disease accompanied by immune imbalance, accompanied by an increase in some immune parameters and a decrease in others [8, 9, 12, 22].

In our study, there was a significant decrease in CD3, CD4, CD8, CD20, CD23, CD25, CD95 levels and an increase in CD16 and total IgE compared with healthy individuals. Against the background of Xolar treatment, there is a significant decrease in the absolute index of CD8, CD16 and CD23, a twofold increase in total IgE and a downward trend in the remaining indicated indicators, which indicates a suppressive effect of the drug on cellular immunity in atopic asthma.

CD3, a marker of the surface of T cells, plays a role in both the development and exacerbation of asthma. In particular, an increased level of CD3+ cells, especially CD3+CD8+, in the respiratory tract is associated with decreased lung function in patients with asthma. Moreover, the effect of antibodies on CD3-mediated signaling pathways has shown effective results in suppressing lung inflammation and reducing the effects of asthma exacerbations caused by allergens [13,19].

CD8 cells play a leading role in the immunopathogenesis of such a heterogeneous disease as BA, causing the intercellular cooperation of the immunopathological response, as well as the interaction between other blood cells, in particular eosinophils, causing the development of the pathological stage of asthma. Omalizu mab, by inhibiting the production of free IgE, makes it impossible to develop the pathochemical stage, and as a result, improves the condition of patients, making it impossible to develop asthma attacks. Due to the suspension of pathogenesis and disruption of intercellular immune cooperation, CD8 levels decrease in our study [8, 14, 18].

Natural killer cells (CD16) are involved in all immunopathological processes, ensuring the stability of homeostasis. The protective effect of killers is to enhance the apoptosis of eosinophils and basophils and to destroy, as far as possible, IgE [17]. Due to the disruption of the intercellular cooperation of the immune response, the level of natural killer's decreases.

CD23 are lymphocytes responsible for participating in allergic reactions. It is known that a low-affinity FceRII receptor is present on the surface of CD23, which binds to IgE and plays a role in the presentation of IgE in allergic reactions and interaction with B cells. Due to the heterogeneity of the immunopathogenesis of asthma, the issues of intercellular cooperation of immune interaction between both blood cells and bronchial epithelium and between these media continue to be studied [8,12]. Probably, when using Omalizumab, an indirect decrease in their level should be expected due to both an indirect decrease in the level of free IgE, which affects the intercellular cooperation of the immune response, and an effect on individual subpopulations of lymphocytes. We have not found any information in the available literature on the effect of Omalizumab on CD23. This may indicate local features of immunity and immune response during treatment with this drug.

Despite the fact that a decrease in CD95, CD25, and CD4 is a well-known fact in atopic asthma, our study shows a downward trend in these indicators after Omalizumab, which is probably due to the influence of regional features (climate) and a change in the nature of intercellular cooperation [7, 9].



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There was a significant twofold increase in IgE levels after single administration of Omalizumab against the background of clinical improvement. Due to the blocking of free IgE, there is an increase in the level of bound IgE, described earlier by researchers at the beginning of this century. This increase is due to depletion of free IgE and release of bound IgE, which Omalizumab has no effect on. Due to the blocking of the allergic component of inflammation (free IgE), the anti-inflammatory effect of Omalizumab is manifested, leading to a decrease in ESR and a decrease in white blood cell levels. The effect of Omalizumab on the level of eosinophils in both peripheral blood and sputum of asthma patients is less pronounced.

This decrease occurs due to disruption of the eosinophil-free IgE communication and was described earlier. And the lack of a reaction of basophils to the drug is due to the fact that it is not an antihistamine (basophils produce histamine) and does not act on the level of general IgE [5,15,22].

An important factor should be noted that when Omalizumab was used, significant clinical improvement in the condition of asthma patients was noted in the form of cessation of seizures, relief or reduction of shortness of breath [2, 3, 5, 7, 23].

It is well known that the course of BA and the response to treatment depend on climatic and geographical conditions and the local landscape of the allergens. Therefore, the course of BA and the response to treatment, including clinical and immunological, will differ slightly from the course of asthma in European Russia, Central Europe, or South America [1,3,4]. The dependence of the course of asthma on temperature, humidity, wind presence, altitude above sea level, and air dustiness, which affect both the course of the disease and immunological parameters, has been revealed [16, 21]. That is why the decrease in the level of killers is probably a regional geographical feature of Uzbekistan.

It should also be noted that Xolar treatment of patients with atopic asthma continues.

**Conclusions**:

1. The use of Omalizumab in patients with atopic asthma leads to a decrease in the content of eosinophils and leukocytes.
2. Omalizumab reduces CD8, CD16, and CD23 levels in atopic asthma.
3. A single application of Omalizumab leads to an increase in the level of total IgE in patients with atopic asthma with clinical improvement.

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**Contribution of the authors:**

Suyarov A.A. - general idea, general guidance, scientific design and writing of the article;
Khatamov H.M. – selection of patients, statistical processing;
Kireev V.V. – statistical processing, scientific design and writing of the article;
Ochilov S.I. - selection of patients.



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