Experience of using the drug upadacitinib in a child with severe atopic dermatitis

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Abstract

Introduction. Atopic dermatitis (AtD) is a genetically determined chronic dermatosis with heterogeneous manifestations that can significantly affect the quality of life of patients. The disease has a complex pathogenesis, which significantly complicates its treatment. The JAK-STAT signaling pathway plays a central role in the modulation of several immune axes involved in the immunopathogenesis of AtD. In particular, the action of Th2 cytokines, including IL-4, IL-5, IL-13, IL-31 and thymus stromal lymphopoietin, is mediated by transmission of the JAK-STAT signal, which makes this pathway a good target for targeted drugs.
Presentation of the clinical case. At the present stage, the problem of choosing tactics for the treatment of severe forms of ATD is important. In June 2021, the drug upadacitinib, a selective reversible type 1 janus kinase inhibitor, was registered in the Russian Federation for the treatment of moderate to severe AtD in adults and children 12 years and older. This publication presents our own successful experience of using upadacitinib in the form of a description of a clinical case in a 16-year-old child with uncontrolled severe AtD. Before the drug was prescribed, the patient's disease course was continuously recurrent, with severe exacerbations and short periods of remission, as well as resistance to standard therapy.
Conclusion. The use of upadacitinib at a dose of 15 mg for 11 months allowed the teenager to achieve rapid remission of the disease and successfully control such a complex symptom as itching.

Keywords: atopic dermatitis, upadacitinib, targeted therapy

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Опыт применения препарата упадацитиниб у подростка с тяжелым течением атопического дерматита

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Аннотация

Введение. Атопический дерматит (АтД) представляет собой генетически детерминированный хронический дерматоз с гетерогенными проявлениями, которые могут существенно влиять на качество жизни пациентов. Заболевание имеет сложный патогенез, что существенно затрудняет его лечение. Центральную роль в модуляции нескольких иммунных осей, участвующих в иммунопатогенезе АтД, играет сигнальный путь JAK-STAT. В частности, действие цитокинов Th2, включая IL-4, IL-5, IL-13, IL-31 и стромальный лимфопоэтин тимуса, опосредуется передачей сигнала JAK-STAT, что делает этот путь удачной мишенью для таргетных препаратов.

Изложение клинического случая. На современном этапе немаловажной является проблема выбора тактики лечения тяжелых форм АтД. В июне 2021 г. в РФ для лечения среднетяжелого и тяжелого АтД у взрослых и детей от 12 лет и старше был зарегистрирован препарат упадацитиниб — селективный обратимый ингибитор янус-киназы 1-го типа. В данной публикации представлен собственный успешный опыт применения упадацитиниба в виде описания клинического случая у ребенка 16 лет с неконтролируемым тяжелым течением АтД. До назначения препарата течение заболевания у пациента было непрерывно-рецидивирующим, с тяжелыми обострениями и короткими периодами ремиссии, а также резистентностью к стандартной терапии.

Заключение. Применение упадацитиниба в дозе 15 мг в течение 11 месяцев позволило добиться у подростка быстрой ремиссии заболевания и успешно контролировать такой сложный симптом, как зуд.

Ключевые слова: атопический дерматит, упадацитиниб, таргетная терапия

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Atopic dermatitis (AtD) is a multifactorial genetically determined dermatosis with a complex pathogenesis characterized by pruritus, chronic recurrent course, and age-related localization and morphology of lesions [1]. It is one of the most common skin diseases: according to the Federal Statistical Surveillance, in 2018, the incidence of AtD in the Russian Federation amounted to 188.2 cases, and the prevalence was 426.3 cases per 100,000 of the total population [2].

AtD usually develops in the first 2 years of life and in 20% of cases persists into adulthood [3]. Severe course significantly worsens the quality of children's life, causing frequent school absences, depression, se-

rious problems in the family, and social maladaptation in adulthood [4, 5].

Due to the fact that bronchial asthma (BA) and allergic rhinitis have a common pathophysiological connection with AtD, it can serve as a starting point for the development of the "atopic march" — a typical sequential progression of allergic diseases from AtD with concomitant food allergy in most cases to the formation of further BA and allergic rhinitis with the expansion of the sensitization spectrum [6].

The pathogenesis of AtD results from a combination of genetic and environmental factors that cause skin barrier dysfunction, cutaneous and systemic immune dysregulation, and disruption of the skin and gut microbiota [5].

Abnormal cytokine production plays a crucial role in pathogenesis [7]. The imbalance of pro- and anti-inflammatory signals stimulates a vicious circle, causing skin inflammation, pruritus and secondary epidermal barrier disruption [8]. AtD is a biphasic inflammatory process mediated by T cells. In the acute phase of the disease, the Th2 response with subsequent hyperproduction of specific IgE predominates; as the process becomes chronic, the immune response switches to Th1. Epidermal cells play an important role in the pathogenesis of AtD. The skin barrier defect induces the release of mediators by keratinocytes, such as TSLP, IL-25, IL-31, which causes increased production of cytokines: IL-4, IL-5, IL-13 and IL-31, contributing to local inflammation [3, 8]. Of note, most of the aforementioned inflammatory cytokines utilize the janukinase (JAK)/signal transducer and activation of transcription (STAT) pathway for subsequent signal transduction, making this pathway a successful target for targeting drugs [9].

ЛAtD treatment should have a complex and individual approach depending on age, prevalence of the skin process, severity of the disease and anamnestic data, including the elimination of provoking factors (irritants, allergens, stress), anti-inflammatory external treatment, control of the infectious process in the presence of complications, skin moisturizing with the restoration of the epidermal barrier [10].

The priority therapy for AtD is topical treatment with topical glucocorticosteroids (GCS), calcineurin inhibitors, and emollients. However, moderate to severe AtD may be associated with systemic immune activation, which explains the insufficiency of topical skin therapy and necessitates the use of systemic agents [4].

Until recently, the choice of systemic therapy for severe AtD was limited to the use of systemic GCS and cyclosporine. According to modern Russian and foreign clinical guidelines, recombinant monoclonal antibodies of the IgG4 isotype directed against the common subunit of the receptor for IL-4/13 and blocking the effects of IL-4 and IL-13 can be used in moderate to severe AtD in the absence of effect from standard methods of treatment. Dupilumab is the first biologic to inhibit IL-4 and IL-13 receptor activation in severe and moderate AtD [3].

Currently, the possibilities of systemic therapy for AtD patients have been expanded. In June 2021, the drug upadacitinib, which is a selective reversible inhibitor of type 1 janukinase, was registered in the Russian Federation for the treatment of moderate-to-severe AtD in adults and children aged 12 years and older. Upadacitinib (UPA) has undergone an extensive program of phase 2 and 3 clinical trials to evaluate its efficacy and safety in AtD before its introduction into clinical practice [11]. Registration studies involving adult patients and children over 12 years of age with moderate to severe AtD have been completed to date.

This article presents the experience of using the targeting drug upadacitinib in a 16-year-old patient with severe atopic dermatitis.

CLINICAL CASE

Patient M., 16 years old, was admitted to the Orenburg Regional Children's Clinical Hospital in May 2023 with complaints of widespread rashes accompanied by intense itching, pronounced dryness of the skin, scaling, scratching, chapped skin. According to the teenager's words, the skin is "red", flaky, rashes are constant ("there is no such thing as clean skin"), and he is concerned about itching at night, which disturbs his sleep. Due to his severe condition, the patient has to stay at home all the time, and he does not attend school.

Past medical history: child from the 1st pregnancy with toxicosis, 1st term delivery. Birth weight 4248 g, height 52 cm. He was breastfed until the age of 1 year. Vaccinated according to the calendar plan. Sick with ARI 2-3 times a year.

Allergologic history: heredity for allergic diseases is aggravated: the maternal grandmother has allergic rhinitis. The child has intolerance to food products (honey, chicken egg, citrus fruits, sweets), appearing with rashes, erythema, itching.

Disease history: skin rashes began to appear from the first months of life, atopic dermatitis was diagnosed, which was exacerbated 3-4 times a year (most often in the cold season), associated with errors in diet, acute respiratory tract infections.

During exacerbations he received sorbents, antihistamines, topical GCS, emollients. At the age of eight, nasal congestion and rhinorrhea began to appear in spring and summer, and seasonal allergic rhinitis was diagnosed. Several times the child suffered bronchitis with bronchial obstruction syndrome, the symptoms were treated with inhalations of berodual and pulmicort via nebulizer. Allergologic examination in 2018 revealed specific IgE to a mixture of house dust mites, a mixture of epidermal allergens of pets, tree pollen and meadow grasses. Allergy-specific therapy was not performed due to frequent severe exacerbations of AtD. In case of exacerbation of seasonal allergic rhinitis he received symptomatic therapy with a temporary effect. The child is observed by an allergist and immunologist at the place of residence, has been repeatedly hospitalized in Orenburg State Autonomous Institution of Health Care "OCCH". During hospitalizations he received treatment: systemic GCS intravenous drip, antihistamines, external therapy with topical GCS, emollients without any pronounced effect. Since 2021, the course of the disease worsened, which the patient himself attributes to the coronavirus infection, exacerbations of atopic dermatitis became monthly, the disease continuously recurred. Severe course of AtD and presence of concomitant allergic diseases was an indication for the patient to receive a disability group.

In 2023, the child was first diagnosed with a concomitant disease: according to EGD data, non-atrophic antral gastritis was diagnosed.

On admission, the condition is severe due to a pronounced skin syndrome, excoriating pruritus. The skin pathological process has a diffuse symmetrical character; it is localized on the skin of the face, neck, trunk, upper and lower extremities; is represented by multiple erythematous-squamous foci, serous-hemorrhagic crusts, excoriations, lichenoid desquamation with linear scaling over the entire skin surface, in the elbow folds, hamstring fossa and on the wrist joints — lichenification; on the face periorbital shadows. The area of the pink border of the lips is chapped and flaked as manifestations of cheilitis. Persistent white dermographism. Diffuse hyperemia of the skin, pronounced dryness. The skin is rough, rough to the touch, tissue turgor is preserved, skin elasticity is reduced. There are no signs of secondary infection. Scoring of Atopic Dermatitis (SCORAD) index — 84.7. Peripheral lymph nodes are not enlarged. Nasal breathing is difficult on both sides. There is a clear lung sound over the whole surface of the lungs. Vesicular breathing, no rales are heard. Respiratory rate 16 per minute. Heart tones clear, rhythmic. HR 72 per minute. BP 110/70 mm Hg. The abdomen is soft, painless on palpation. Liver, spleen are not enlarged. Stools are regular without pathologic impurities. Urination is painless. Thyroid gland is visually not enlarged, painless on palpation.

Laboratory tests on admission. No change in general clinical examinations.

Total IgE was found to be elevated — 1159.0 IU/mL (0.0-100.0 IU/mL). Specific IgE with a panel of food allergens: egg white — class 3; egg yolk, carrot, rye, mandarin, sunflower seed, potato — class 1.

Immunoglobulins A, M, G in serum: elevated IgA 2.54 g/l (N: 0.07-0.94 g/l). No evidence of helminthiasis and giardiasis was obtained during laboratory examination.

Thyroid hormones (TTG, T4): decreased free thyroxine — 9.1 pmol/l (N: 10.0-23.2 pmol/l) was detected.

Instrumental studies. ECG: sinus rhythm, HR 72 per minute. Spirometry: all indices are within normal limits. Ultrasound examination of abdominal cavity organs, thyroid gland and parathyroid glands: no pathology revealed.

On the basis of complaints, medical history, clinical picture and examination results the diagnosis was made: «Atopic dermatitis, adolescent form (diffuse neurodermatitis stage), widespread, severe, with eczematization, exacerbation. Seasonal allergic rhinitis, medium severity, persistent course, remission. Polyvalent sensitization. Chronic non-atrophic non-atrophic antral gastritis, remission. Subclinical hypothyroidism».

Inpatient treatment was provided: chloropyramine 2% 1 ml 2 times a day intramuscularly, prednisolone 60 mg intravenous drip in 500 ml of 0.9% NaCl solution, cetirizine 10 mg intravenously, skin UVI. Topical therapy: Acriderm GC 2 times a day on the affected areas of the skin of the trunk, upper and lower extremities, emollients of the Admera series of medical cosmetics. The effect of the treatment was insignificant: itching decreased slightly, fissures epithelialized, at discharge SCO- RAD — 50.1.

Due to the severe course of atopic dermatitis in the patient and the lack of effect from therapy, a discharge letter was sent to the Federal Center of "FRC Nutrition and Biotechnology", Moscow to consider the issue of target therapy, where the child was recommended to start therapy with the drug upadacitinib 15 mg/day orally for 12 months for vital indications.

In June 2023 the patient started taking UPA, also continued the use of topical GCS and emollients. Against the background of the therapy a significant improvement in the boy's well-being was noted: already in the first days of taking the drug he noted a decrease in the intensity of pruritus (from 10 to 5 points on NRS).

Accordingly, the significant primary effect of therapy was the normalization of sleep and daytime activity and, as a consequence, the restoration of normal psycho-emotional state and improvement of the patient's quality of life.

At examination after 1 month, significant positive dynamics was observed: the severity and area of skin rashes decreased, cracks in the elbow bends and hamstrings disappeared, the skin became more elastic, its dryness and desquamation decreased. Reduced itching and inflammatory changes also contributed to the cessation of scratching and healing of excoriations. SCORAD index at the time of examination 30.5. No adverse events were observed against the background of UPA administration. Dynamic evaluation of laboratory parameters (total blood count, urinalysis, biochemical blood count) did not reveal any deviations in the course of treatment. Given the rapid and significant effect, the patient had high adherence to the continuation of the prescribed therapy. At the moment the patient has been receiving the drug for 11 months. The adolescent has almost clear skin on the background of UPA intake.

In May 2024, against the background of acute respiratory viral infections and discontinuation of the drug, the boy's condition worsened, and he was hospitalized in the Orenburg Children's Clinical Hospital. Examination revealed erythematous-squamous foci on the skin of the face, trunk, upper and lower extremities. In the area of elbow bends, hamstring fossae, wrist joints — lichenification, hemorrhagic crusts, excoriations. SCORAD — 56.2. In the blood serum there was detected an increase in the total IgE level up to 2012 IU/mL.

Treatment was carried out: dexamethasone 8 mg diluted in 500 ml of 0.9% NaCL solution by IV drip #3, cetirizine 10 mg once a day, upadacitinib 15 mg once a day, externally Comfoderm once a day for rashes. On the background of the therapy the rashes regressed, SCO- RAD index at discharge — 27,6.

The statement was repeatedly sent to the Federal Center of "FRC Nutrition and Biotechnology" for extramural consultation to address the issue of prolongation of UPA target therapy, the answer has not been received yet.

Thus, the presented clinical case demonstrates the positive result of the use of UPA, a new drug for the treatment of AtD, which allowed the patient to achieve rapid remission of the disease and successfully control such a difficult symptom as pruritus. It is important to note that UPA not only showed high clinical activity, but, no less importantly, did not cause adverse events in the patient, which could cause the drug discontinuation.

AtD therapy should be comprehensive and individualized, taking into account the age of the patient and the severity of the disease. To prevent disease progression to more severe, disabling forms, it is necessary to create new treatment paradigms. Expansion of the spectrum of pathogenetic therapy of AtD with inclusion of the inhibitor of Janukinase type 1 UPA fully corresponds to modern trends. Upadacitinib has a good evidence base, its clinical efficacy and safety have been proven in many clinical trials, which allows its use for the therapy of moderate and severe AtD in both adults and adolescents 12-18 years old.

Our experience with UPA shows the high efficacy of daily administration of 15 mg of the drug for 11 months. Against the background of treatment, the adolescent showed significant positive dynamics: a rapid decrease in the activity of clinical symptoms, stability of the achieved results and absence of side effects. The skin remained practically clean, the reduction of itching contributed to a favorable emotional state and normalization of the patient's sleep. Due to the patient's good response to treatment and the occurrence of exacerbation upon withdrawal of UPA, there is a need to continue therapy with this drug.

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THE AUTHORS' CONTRIBUTION TO THE WORK

Galina D. Alemanova — examination and treatment of patients, collection of clinical material, writing a manuscript.

Larisa Yu. Popova — examination and treatment of patients, collection of clinical material, approval of the manuscript.

Elena A. Zlodeeva — review of publications on the topic of the article.

Olga V. Kirichenko — review of publications on the topic of the article, writing a manuscript.

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CONSENT FOR PUBLICATION

Written consent for publication of relevant medical information within the manuscript was obtained from the patients and patient's parents.

ИНФОРМИРОВАННОЕ СОГЛАСИЕ НА ПУБЛИКАЦИЮ

Пациенты и их законные представители добровольно подписали информированное согласие на публикацию персональной медицинской информации в обезличенной форме.