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ANIFROLUMAB IN THE TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS - A LITERATURE REVIEW

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ABSTRACT

Introduction and objective: Systemic lupus erythematosus (SLE) is a chronic, autoimmune disease characterised by a diverse clinical course and multifactorial aetiology. Improvement in treatment has been significant in recent years. Current treatment is primarily based on glucocorticosteroids and immunosuppressive drugs that cause numerous side effects and have limited efficacy in a significant number of patients. Anifrolumab therapy is a new treatment option in SLE. The aim of this review is to describe its characteristics, mechanisms of action, and therapeutic effects.
Review methods: A literature review was conducted using scientific publications, focusing primarily on those published between 2017 and 2025. The PubMed and Google Scholar databases were used for the search. Publications in English and Polish that met thematic and substantive criteria were analyzed. Ultimately, 32 publications were included in the review
Brief description of the state of knowledge: Anifrolumab is a modern monoclonal antibody that blocks the type I interferon pathway, one of the key mechanisms in the pathogenesis of SLE. A significant reduction in disease activity, improvement in joint and skin symptoms, and a reduction in glucocorticosteroid use can be achieved.
Summary: Anifrolumab represents a novel approach in the treatment used in moderate to severe forms of SLE. This drug improves skin and joint symptoms, reduces disease activity, and reduces used doses of corticosteroids. It is well-tolerated and has a rapid therapeutic effect. It improves patients' quality of life. However, its safety in use in children, pregnant and breastfeeding women is unknown.

KEYWORDS

Interferon Type I, Monoclonal Antibodies, Autoimmune Diseases, Pharmacokinetics, Systemic Lupus Erythematosus

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Introduction

Systemic lupus erythematosus (SLE) is a heterogeneous autoimmune disease with diverse possible clinical presentations and courses. SLE can simultaneously affect multiple organs. In general, it is characterised by chronic inflammation in various tissues, deposition of immune complexes, and the presence of autoantibodies directed against nuclear antigens. Significant dysregulation of the cellular and humoral immune responses occurs, leading to the production of proinflammatory cytokines, such as interleukin-1, interleukin-6, and interferon-gamma, which perpetuate high levels of inflammation and contribute to tissue damage and fibrosis [1]. The diagnosis of lupus is based on the presence of numerous clinical symptoms that rarely co-occur and can develop at different stages. This can delay the diagnosis. In the early stages, patients complain of nonspecific symptoms, such as fever, joint pain, or chronic fatigue. A characteristic butterfly-shaped rash and joint swelling also raise suspicion [2]. According to the 2018 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) classification criteria, a diagnosis of SLE is possible after scoring at least 10 points from the clinical and immunological domains, provided that at least one clinical criterion is met and the patient has a confirmed antinuclear antibodies (ANA) titer above 1:80. There are seven clinical criteria, including the constitutional, cutaneous, neurological, hematological, renal, arthritis and/or serositis domains, and three immunological criteria. The last mentioned type of criteria takes into account the presence of antiphospholipid antibodies, highly specific autoantibodies for SLE - anti-dsDNA and anti-Sm, and the concentration of complement components C3 and C4. For each component, the patient receives a specific number of points, which are then summed to determine whether the score exceeds the threshold necessary for diagnosis [3,4]. The incidence of SLE is increasing, with a rate ranging from 20 to 150 cases per 100,000 people worldwide. Skin lesions occur in almost 70% of cases. Cutaneous manifestations of lupus are divided into subtypes based on clinical features, histological changes, and serological abnormalities. There are several subtypes of cutaneous lupus erythematosus: acute, subacute, chronic, and intermittent. The severity of SLE is assessed by the Cutaneous Lupus Area and Severity Index (CLASI) [5]. SLE is characterised by the presence of diverse autoantibodies targeting nuclear components and systemic inflammation, leading to multiorgan damage. Abnormal B-cell maturation and activation play a crucial role in the immunopathogenesis of SLE, both in antibody-dependent and antibody-independent mechanisms [6,7]. Antimalarials, glucocorticosteroids, mycophenolate mofetil, methotrexate, azathioprine, calcineurin inhibitors, and biologics are used in the treatment of SLE [6]. Due to the chronic use of glucocorticoids in the treatment of SLE, patients are exposed to the risk of numerous adverse effects, such as impaired glucose tolerance, weight gain, development of abdominal obesity, muscle weakness, hypertension, exacerbation of heart failure, oedema, risk of gastric and duodenal ulcers, increased risk of infection, osteoporosis, increased intraocular pressure (glaucoma), development of cataracts, and hypothyroidism [8]. The complex pathogenesis and heterogeneity of the clinical presentation pose a significant challenge to the treatment of lupus [6,9]. Although therapeutic regimens have evolved over the years, they still have substantial limitations, including a significant risk of adverse events and a high relapse rate. Given the negative effects, the authors emphasised the need to develop targeted therapeutic strategies for SLE [10,11]. The occurrence of exacerbations, target organ involvement, inadequate response in some SLE patients to conventional immunosuppressive therapy, and adverse effects of widely used immunosuppressive drugs have led to the introduction of biologic agents in the treatment of SLE [12]. They target various pathogenetic pathways. In particular, agents targeting B cells, interferon (IFN), and tumour necrosis factor alpha (TNF-α) inhibitors are being investigated [13]. Biologic agents that have demonstrated beneficial effects in SLE include belimumab, anifrolumab, ustekinumab, and rituximab (RTX), which is used off-label [14]. This article focuses on anifrolumab.

Mechanism of action

Anifrolumab is a human IgG1 kappa monoclonal antibody that binds to the IFNAR1 subunit - a component of the type I interferon receptor (IFN-I) [15], while inhibiting type I interferon signaling, which is involved in both innate and adaptive antiviral responses in various cell populations [16–18]. Anifrolumab inhibits the binding of type I interferons to IFNAR, thereby preventing activation of the JAK-STAT signaling pathway and the subsequent transcription of interferon-stimulated genes, which mediate immune responses. Furthermore, by targeting the receptor involved in cell signalling, anifrolumab reduces the activity of several interferons, including interferon alpha (IFN-α), interferon beta (IFN-β), interferon epsilon (IFN-ε), interferon kappa (IFN-κ), and interferon omega (IFN-ω) [16,19]. Anifrolumab contains a triple mutation (L234F/L235E/P331S) in the Fc region of the heavy chain, which limits binding to Fc receptors to the cell surface. This minimises antibody-dependent effector functions (effector-null), such as antibody-dependent cellular cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) [20].

Methods

A literature review was conducted based on an analysis of available scientific articles concerning the use of anifrolumab in the treatment of systemic lupus erythematosus. The search was performed using keywords related to anifrolumab use in SLE therapy. Data sources included the electronic databases PubMed and Google Scholar. The initial selection of publications was based on keyword and abstract screening, and articles not directly related to the study topic were excluded. A total of 32 publications directly addressing anifrolumab therapy or describing the pathomechanisms of SLE were included in the final analysis. The review focused primarily on studies published between 2017 and 2025, while also incorporating highly cited earlier works. Only publications in Polish and English were considered. The article selection process began with an analysis of titles, keywords, and abstracts, followed by a detailed assessment of full-text articles that met the inclusion criteria. Finally, the selected publications were evaluated for their relevance, alignment with the study topic, and overall scientific value.

Literature review

Based on the results of the Phase 2 MUSE study and two Phase 3 studies, TULIP-1 and TULIP-2, anifrolumab was approved for the treatment of adult patients with moderate to severe SLE [15]. The MUSE study was the first large clinical trial to confirm the efficacy of anifrolumab in the treatment of SLE. It enrolled 305 participants. It was a Phase IIb, randomised, double-blind, placebo-controlled study that assessed the efficacy and safety of anifrolumab in adults with moderate to severe SLE. In patients treated simultaneously with anifrolumab and corticosteroids, skin condition improved, and the frequency of disease flares decreased. A reduction in their oral corticosteroid doses was achieved and sustained for a period of 52 weeks, while maintaining the effects of the treatment. Furthermore, their skin condition improved, and the frequency of disease flares decreased [16,19,21]. The combined pharmacokinetic and pharmacodynamic data about anifrolumab, along with its low immunogenicity, demonstrate that overall, the approved dosing regimen of 300 mg intravenous anifrolumab every four weeks provides sufficient drug exposure to maximise benefit while maintaining an acceptable safety profile in SLE patients receiving standard therapy [19,22,23]. Patients treated with anifrolumab demonstrated improved responses across a range of secondary outcomes and clinical endpoints at week 52, including primary clinical response, BICLA (British Isles Lupus Assessment Group-based Composite Lupus Assessment), modified SRI (SLE Responder Index), and SRI [9,18]. In patients who completed the MUSE Phase IIb study and had moderate to severe SLE, anifrolumab was evaluated for tolerability and safety over a three-year period. Adverse events were monitored monthly, and disease activity, damage index, pharmacodynamic parameters, and quality of life were also assessed. Almost 90% of the study participants (88.6%) entered the open-label extension, and 63.8% completed the full three-year treatment period. In the first year, 69.7% of patients reported at least one adverse event. Regarding adverse events, patients reported a higher incidence of viral infections, such as varicella zoster, nasopharyngitis, bronchitis, and influenza. Only 6.9% discontinued treatment, and no new safety concerns emerged. In the high IFN population, sustained reduction in disease activity and neutralisation of the IFN-I gene signature were observed. Long-term anifrolumab treatment was well tolerated. Multiple studies reported continued improvement in serological markers, increased quality of life, and decreased SLE disease activity [9,19,20].

The efficacy of anifrolumab was further evaluated in global phase III clinical trials (TULIP 1 and TULIP 2) [9,20]. Both studies were 52-week randomised, placebo-controlled trials, in which anifrolumab was administered intravenously every 4 weeks. In TULIP 1, the anifrolumab and placebo groups did not

demonstrate statistically significant differences in the primary endpoints, particularly in response to British Isles Lupus Assessment Group–based Composite Lupus Assessment (BICLA). However, the TULIP2 study demonstrated that treatment significantly improved BICLA response at week 52, independent of IFN status. Furthermore, the TULIP 2 study demonstrated significant improvements in important secondary outcomes, including a reduction in a daily glucocorticoid dose to ≤7.5 mg, sustained from weeks 40 to 52, a ≥50% reduction in CLASI at week 12, a ≥50% reduction from baseline in the number of swollen and tender joints at week 52, and an annualized flare rate by week 52 [9,21]. Anifrolumab demonstrated efficacy in the treatment of SLE, achieving statistically significant results in secondary endpoints as well, conversely to other biological agents like rontalizumab and sifalimumab. Regarding safety, adverse events were similar between the drug and placebo groups. Only the incidence of viral infections, such as shingles, chickenpox, and respiratory infections, was higher in the anifrolumab group. Therefore, individual risk assessment and consideration of vaccinations are recommended before initiating therapy [24,25]. After 12 weeks of treatment, 46% of patients receiving anifrolumab achieved a >50% reduction in their CLASI score, compared with 24.9% in the placebo group, indicating a significant improvement in skin involvement [20]. An advantage of anifrolumab treatment is the rapid induction of clinical improvement. Achieving a quick therapeutic effect helps to limit the development of scarring alopecia, scars, and depigmented areas, as they tend to develop over time. These changes can impact patients' daily lives. Anifrolumab can also effectively alleviate mucosal symptoms, which are among the most difficult symptoms of lupus to treat [3,26].

The literature describes 20 publications covering a total of 78 patients with cutaneous lupus erythematosus (CLE) who were treated with anifrolumab. In discoid lupus erythematosus, a chronic form of cutaneous lupus erythematosus, a complete response was achieved by 62.5% of 58 patients. In subacute cutaneous lupus erythematosus, a complete response was observed in 76.9% of 17 patients. Improvement was usually noticeable after the first dose. Complete improvement was also observed in other types of cutaneous lupus. Individual cases of effective use of anifrolumab in lupus tumidus and Rowell's syndrome have also been described [20].

Anifrolumab demonstrates advantages over the previously used biologic drug, belimumab. One American study reported that two patients in whom belimumab was replaced with anifrolumab experienced significant improvement in their skin lesions [5]. The TULIP-LN study evaluated the efficacy and safety of anifrolumab in the treatment of lupus nephritis. In patients with active class III or IV lupus nephritis, the addition of an intensified anifrolumab regimen to standard therapy with mycophenolate mofetil and glucocorticoids improved renal outcomes [27].

Anifrolumab also improves patients' quality of life. Danish studies conducted 3 and 6 months after treatment initiation assessed the symptoms reported by patients and the negative impact of the disease on daily life before and after treatment. Preliminary studies involved 14 patients, whereas data from electronic medical records were collected from 16 patients treated for 62 to 474 days. Before anifrolumab treatment, some of the most common symptoms were fatigue, joint pain, sun sensitivity, joint stiffness, skin rashes, and hair loss. Most symptoms improved significantly during treatment, and none worsened. Patients reported that the disease had a substantial impact on daily activities, social life, emotional aspects, physical activity, concentration and memory, employment, and family and romantic relationships before treatment. After anifrolumab treatment, patients reported improvements in all these aspects [28,29]. Use of anifrolumab allows a reduction in steroid dosage, but this is not its only advantage. It also improves laboratory test results by reducing complement C3 levels and lymphocyte counts [28].

The FDA has approved anifrolumab for the treatment of moderate to severe lupus erythematosus, excluding patients with central nervous system involvement or lupus nephritis. It was also approved by the European Medicines Agency (EMA) in 2022 as an additional treatment option for adult patients with moderate to severe SLE despite conventional therapy [3,12]. The drug reduces disease activity and improves clinical outcomes in patients with moderate to severe SLE [24,25].

Pharmacokinetics

Based on data from studies in adult SLE patients, following intravenous administration of doses ranging from 100 to 1000 mg every 4 weeks, anifrolumab exhibits nonlinear pharmacokinetic properties. The increase in blood concentration is not proportional to the dose increase. In healthy volunteers receiving 300 mg of intravenous anifrolumab every 4 weeks, plasma concentrations of the drug increased until day 85, after which they remained at a steady level. The approximate accumulation ratio for maximum plasma concentration (Cmax) was 1.36, indicating that the maximum drug concentration after multiple doses was approximately 36%

higher than after the first dose. Based on a population pharmacokinetic analysis in a standard 69.1 kg lupus patient, the estimated steady-state volume of distribution was 6.23 litres. This indicates that anifrolumab remains primarily in the bloodstream and extracellular fluid, without accumulating in tissues. Drug clearance is regulated by IFNAR1 and does not exhibit linear pharmacokinetics at higher doses. The estimated systemic clearance (CL) of anifrolumab was 0.193 liters per day. This level of clearance represents slow elimination of the drug, allowing dosing every 4 weeks [30].

Pregnancy and breastfeeding

Anifrolumab is classified as a category C drug in pregnancy, and evidence regarding its safety in pregnant women remains limited. As an IgG monoclonal antibody, anifrolumab is expected to cross the placenta, with transplacental transfer increasing progressively throughout gestation and reaching its highest level during the third trimester. Consequently, potential risks such as congenital malformations, miscarriage, or adverse maternal and fetal outcomes cannot be excluded, particularly when exposure occurs later in pregnancy [30]. There is no data on the clinical use of anifrolumab during breastfeeding. Due to its large molecular size, the transfer of anifrolumab into breast milk is expected to be minimal. It may be degraded in the infant's gastrointestinal tract and is likely minimally absorbed [30,31].

Side effects

In clinical studies, patients receiving anifrolumab experienced a higher incidence of certain adverse events, most commonly upper respiratory tract infections, nasopharyngitis, infusion-related reactions, bronchitis, and urinary tract infections. Other reported events included sinusitis, arthralgia, back pain, and cough. Of note, herpes zoster occurred more frequently in the anifrolumab group than in the placebo group [30,32]. Due to the adverse event profile of anifrolumab, prescribers should exercise caution in patients with active infection or a history of herpes zoster. Data show no significant differences in the incidence of serious non-opportunistic infections, influenza, malignancies, serious cardiovascular events, or tuberculosis between the experimental and control groups [30]. Currently, there is no data on the use of anifrolumab in pediatric patients. Data in geriatric patients, aged 65 years and older, is limited [3]. Clinical trial data on the use of anifrolumab in patients with renal or hepatic impairment are also lacking. Many live vaccines are also contraindicated for concomitant use with anifrolumab, for example, intranasal administration of influenza, dengue, cholera, smallpox, MMR, and varicella vaccines. Serious hypersensitivity reactions, including anaphylaxis, have been reported following anifrolumab administration. Cases of angioedema, including other hypersensitivity reactions and infusion-related reactions, have also been reported. Premedication before infusion is recommended for patients with a history of these reactions. Coadministration of anifrolumab with other biologic therapies is not recommended because this combination has not been studied [30].

Limitations

In the MUSE and TULIP-1 studies, an increase in the incidence of serious adverse events was observed at higher doses of anifrolumab, which led to study discontinuation. However, the statistical significance of these data has not been assessed. To date, no clear serum concentration of anifrolumab has been identified that predicts efficacy and toxicity. In routine clinical practice, serum drug concentrations are not typically measured, and the utility of such monitoring remains unclear. There is also no antidote for this drug [30].

Current Situation and Future Research

Since September 1, 2023, anifrolumab has been available in Poland under the drug program. It is reimbursed for patients with moderate to severe SLE. Its primary indication is as adjunctive therapy in adult patients with seropositive, active SLE who are receiving standard treatment but are inadequate [3]. Phase IV clinical trials may help assess potential toxicity and long-term adverse effects. It can be beneficial if future studies consider the use of the drug in pregnant and breastfeeding women. Pediatric patients and the elderly should also be included [3].

Summary

Despite advances in research, systemic lupus erythematosus (SLE) remains a challenging disease to treat. The management of this condition is challenging due to clinical heterogeneity and complex etiopathogenesis. Introduction of anifrolumab was a breakthrough in the treatment of SLE. This monoclonal antibody blocks the type I interferon receptor, whose activation plays a key role in the pathogenesis of lupus. Numerous clinical trials confirm its effectiveness in reducing disease activity, alleviating the severity of skin symptoms, and joint discomfort. At the same time, the use of this drug enables a reduction in the use of glucocorticoids. Despite excellent clinical conditions and a good safety profile, the therapy has its limitations. Anifrolumab treatment has been associated with adverse reactions, including an increased risk of respiratory tract infections and anaphylaxis. The drug should not be administered to pregnant or lactating women, nor to pediatric patients. Further studies assessing the long-term safety and efficacy of the therapy seem necessary. However, treatment with anifrolumab represents a significant step towards improving patients' quality of life.

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