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New Biologic Therapies in the Management of Psoriatic Arthritis: An Overview

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Abstract

Psoriatic arthritis is an inflammatory musculoskeletal condition that represents a major cause of physical and psychological disability. This disorder represents a significant diagnostic and management challenge, given that it has different forms of clinical presentation, associated comorbidities, and high rates of therapeutic resistance. Early diagnosis is of crucial importance in impacting the prognosis of the disease. Typical treatment includes the administration of non-steroidal anti-inflammatory drugs, disease-modifying anti-rheumatic drugs, and the use of biological medicines. Currently, multiple biological therapies have proven to be advantageous in managing psoriatic arthritis, but they have not been fully approved for use in routine clinical practice. Therefore, in this article, we aim to provide an overview of the role of new biological therapies for the management of psoriatic arthritis.

Keywords: Psoriasis; Psoriatic arthritis; Biologic therapy; New therapies; bDMARDs

Abbreviations: PsA: Psoriasis Arthritis, CASPAR: Classification Criteria for Psoriatic Arthritis, NSAIDs: Non-steroidal anti-inflammatory Drugs, DMARDs: Disease-Modifying Antirheumatic drugs, FDA: Food and Drug Administration, IgG1λ: Immunoglobulin G1 lambda, AS: Ankylosing spondylitis, ACR: American College of Rheumatology, DAPSA: Disease Activity Index for Psoriatic Arthritis, TNFi: Tumor necrosis factor inhibitors, bDMARDs: Biological Disease-Modifying Anti-Rheumatic Drugs, IgG4: Immunoglobulin G4, TB: Tuberculosis, IBD: Inflammatory Bowel Disease, PASI: Psoriasis Area and Severity Index CTL4: Cytotoxic-T-lymphocyte-associated antigen 4, CRP: C-Reactive Protein, COPD: Chronic Obstructive Pulmonary Disease, JAK: Janus Kinase, STAT: Signal Transducer and Activator of Transcription, IL-23: Interleukin 23, BSR: British Society for Rheumatology.

Introduction

Psoriasis arthritis (PsA) is a chronic inflammatory disease that affects the musculoskeletal system [1]. This condition is associated with psoriasis, a skin disease that can be physically and mentally debilitating. It is estimated that approximately 25% of patients with psoriasis develop PsA. Moreover, up to 10% of patients might develop arthritis before presenting other findings of psoriasis [2,3].

Clinical manifestations of PsA include the presence of peripheral inflammatory arthritis, dactylitis, spondylitis, or enthesitis. Additionally, it can lead to extra-articular manifestations such as psoriatic skin plaques, nail disease, fatigue, sleep disturbance, and diminished work capacity [3]. The diagnosis of PsA is mainly based on clinical findings using the Classification Criteria for Psoriatic Arthritis (CASPAR). However, given that the disease can mimic numerous rheumatologic conditions (i.e., rheumatoid arthritis, crystal arthropathies, and osteoarthritis), it often requires the use of laboratory exams and serology tests [3,4].

The management of PsA includes various therapeutic strategies, from using simple non-steroidal anti-inflammatory drugs (NSAIDs) for pain control to employing more complex disease-modifying antirheumatic drugs (DMARDs) [4]. When disease control is not achieved with these drugs, therapies with biological medicines can substantially improve the course of PsA. Biologic therapies include inhibitors targeting IL-23, IL-12, IL-17, TNF, CTLA-4 Ig, and JAK/STAT pathway. Some of these new treatments for psoriasis have shown significant efficacy in PsA [3,5]. However, they have yet to achieve FDA approval. This review study aims to provide a comprehensive overview of the new therapeutic options for PsA to better understand their role in managing this complex condition.

Ustekinumab

Ustekinumab is a fully human monoclonal IgG1 antibody that binds to the p40 subunit shared by IL-12 and IL-23, which prevents the interaction of IL-12 and IL-23 binding to its receptor, blocking the T1 and T17 inflammatory pathways [6,7]. The route of administration recommended subcutaneously is absorbed slowly, and the dosage regimen in adults is an initial dose of 45 mg, then another 45mg at 4 weeks, followed by 45 mg every 12 weeks. For patients with >100 kg, the recommended dose is 90 mg initially, then another 90mg at 4 weeks, followed by 90 mg every 12 weeks [8]. Ustekinumab is approved for adults with moderate to severe plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis in the USA and Europe. It has shown benefits in all essential other types of psoriasis (except plaque psoriasis and psoriatic arthritis), pityriasis rubra pilaris, hidradenitis suppurativa, atopic dermatitis, and pyoderma gangrenosum [6,7]. However, more clinical trials are needed to adequately assess ustekinumab's safety and efficacy for treating these conditions.

Using ustekinumab in psoriatic arthritis has shown clinical efficacy in Phase II and III clinical trials, with a satisfactory safety profile [6]. Common adverse effects include respiratory tract infections, nasopharyngitis, headache, and injection site reactions. Fortunately, severe long-term infections or significant cardiovascular adverse events rarely occur [6,7]. In addition, the therapeutic benefit of ustekinumab appears to be independent of concomitant methotrexate use or previous anti-TNF exposure [6]. There are very limited data on the safety of ustekinumab treatment during pregnancy [9].

Guselkumab

Guselkumab is a human immunoglobulin G1 lambda (IgG1λ) monoclonal antibody that binds with high affinity and specificity to the p19 subunit of IL-23, blocking the activation of the IL-23-mediated signaling pathway and the release of pro-inflammatory cytokines. It is administered subcutaneously and has been approved by the US Food and Drug Administration and the European Medicines Agency for treating moderate-to-severe psoriasis in adult patients [10]. The recommended dosage of guselkumab is 100 mg at weeks 0 and 4, followed by 100 mg every 8 weeks. Patients with clinically critical active infections such as tuberculosis should not receive Guselkumab as it happens with pregnant women due to the lack of information about its safety in pregnancy [11]. In addition, the concomitant administration of live vaccines with guselkumab is not recommended. Guselkumab dose adjustments are not required in elderly patients or according to body weight. The effects of guselkumab on renal or hepatic function have not been studied. However, the preliminary data about reactions has not been relevant [11,12].

In large, randomized, double-blinded, multinational, phase III trials (VOYAGE 1, VOYAGE 2, and NAVIGATE), guselkumab markedly improved disease, regardless of the location of the lesions and the characteristics of the subpopulations. It also showed marked improvements in quality of life measures. In addition, Guselkumab was generally well tolerated. Adverse effects occurred in less than 1% of patients. Common reactions included upper respiratory infections, headache, injection site reactions, arthralgia, diarrhea, gastroenteritis, herpes simplex infections, and tinea infections. To date, the beneficial effects of guselkumab treatment in these trials were maintained for up to 2 years [12].

Secukinumab

Secukinumab is an effective, fully human anti-IL-17A monoclonal that selectively targets and neutralizes circulating and tissue IL-17A. IL-17A is a proinflammatory cytokine produced primarily by T cells but also by natural killer cells, mast cells, and neutrophils that cause inflammation and is usually involved in mucocutaneous defense against extracellular organisms. It is abnormally expressed in psoriasis, and its activity is associated with exacerbations of this disease [13]. In 2015, secukinumab was approved for treating adult patients with moderate to severe plaque psoriasis, psoriatic arthritis, and ankylosing spondylitis (AS) in the US and Europe. The efficacy of secukinumab was evaluated in several phase III, randomized, double-blind, placebo-controlled, multicenter trials: FUTURE 1–5, MAXIMISE, ULTIMATE, and EXCEED (secukinumab vs. adalimumab). It improves clinical signs and symptoms, physical function, and health. Quality of life with sustained benefits for five years is associated with low rates of radiographic progression in patients with PsA regardless of methotrexate use [14]. Secukinumab administered subcutaneously in doses of 150 or 300 mg in regimens with weekly starting doses

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at weeks 0, 1, 2, 3, and 4, with doses of 150 mg or 300 mg every 4 weeks after that, was the scheme that showed better tolerance in clinical trials; assessed both with the American College of Rheumatology response criteria (ACR20) and the Disease Activity Index for Psoriatic Arthritis (DAPSA). Upper respiratory tract infections (nasopharyngitis and rhinitis) were the most common adverse events with secukinumab. Secukinumab should not be administered to patients with active or latent tuberculosis infection [15].

PsA is a chronic and multifaceted disease whose treatment must be individualized, considering factors such as comorbidities, patient preferences, and costs. Secukinumab is recommended in patients with predominantly axial illness as an alternative to tumor necrosis factor inhibitors (TNFi) and other biological disease-modifying anti-rheumatic drugs (bDMARDs).

Ixekizumab

Ixekizumab is a humanized monoclonal immunoglobulin G4 (IgG4) that targets the IL-17 pathway in the pathogenesis of psoriasis. IL-17 contains six isoforms (IL-17A-IL-17F), from which IL-17A is the most potent interleukin involved in psoriasis. Ixekizumab binds to and inhibits IL-17A to prevent the interaction with the IL-17RA receptor and downstream signaling [16]. Ixekizumab is administered via subcutaneous injection. The labeled dosing regimen in adults with PsA consists of a loading dose of 180 mg followed by a maintenance dose of 80 mg every 4 weeks. In contrast, moderate and severe plaque psoriasis requires an "intermediate loading dose" with Ixekizumab 80 mg every 2 weeks for 12 weeks, between the initial loading dose of 160 mg and the final maintenance dose of 80 mg every 4 weeks [17]. Ixekizumab is indicated for moderate-severe psoriasis (including in children aged six and above), psoriatic arthritis, ankylosing spondylitis, and non-radiographic axial spondyloarthritis [17,18]. A Phase II double-blinded, multicenter, randomized, dose-ranging study reported that the most common adverse events were nasopharyngitis, upper respiratory infection, injection-site reaction, and headache. Ixekizumab is contraindicated in patients with active tuberculosis (TB). All patients should be evaluated for TB before a treatment based on risk factors and screened for latent TB before initiation and during therapy. Inflammatory Bowel Disease (IBD) is contraindicated. Consequently, caution should be taken when initiating therapy with Ixekizumab due to the worsening of IBD [18].

A retrospective study that evaluated the efficacy of ixekizumab after failure with secukinumab demonstrated that ixekizumab has greater effectiveness in the treatment of moderate-to-severe psoriasis as well as for slowing radiographic disease progression with ixekizumab than other FDA-approved psoriasis treatment [18]. The US Food and Drug Administration (FDA) approved Ixekizumab in March 2016 to treat moderate-to-severe plaque Psoriasis and in 2017 as the treatment for Psoriatic Arthritis [16,17]. There is currently no available information regarding Ixekizumab use in pregnancy and associated risks. However, human forms of IgG cross the placental barrier. Thus, ixekizumab may be transmitted from the mother to the fetus. Because biological agents may impair the body's immunologic response to vaccinations, the administration of vaccines should be carefully considered in the patients. On the bright side, Ixekizumab does offer significant potential for complete clearance of psoriasis and may become a first-line biologic agent. The main shortcoming of the Ixekizumab PsA program is the lack of representation of African American study participants [16].

Brodalumab

Brodalumab is an available treatment option for moderate to severe psoriasis, especially for patients who have failed topical or systemic therapies. This drug is a monoclonal antibody that inhibits the receptor of IL-17, thus inhibiting proinflammatory IL-17 cytokines produced by T-helper cells [19]. Brodalumab is administered subcutaneously via a prefilled syringe that contains 210mg/15 mL. The subcutaneous injections are administered weekly for the first three weeks, then injected every 2 two weeks [19]. The most common adverse effects reported include the reaction of the injection site, candida infections, nasopharyngitis, and upper respiratory tract infections [19,20]. Other adverse side effects that have been found with brodalumab are arthralgia, gastroenteritis, depression, and increased suicidal ideation [21]. Brodalumab is contraindicated in patients with Crohn's disease, chronic or recurrent infections, children, and pregnant women [19]. Brodalumb has been demonstrated to be effective for skin clearance with a Psoriasis Area and Severity Index (PASI) 100 after 4 weeks in patients with psoriasis and after 6 weeks in patients with psoriatic arthritis [22].

Abatacept

Abatacept is a biological agent produced by recombinant DNA technology that inhibits naive T-cell activation by linking cytotoxic-T-lymphocyte-associated antigen 4 (CTL4) to IG1 and preventing binding between CD28 and CD80/CD86, which modulates co-stimulation [23,24]. It can be administered intravenously or subcutaneously with similar efficiency and safety [3]. Abatacept is administered as a 30 minutes IV infusion at times 0, 14, 28 days, and then every 28 days. The intravenous dose is 10mg/kg, the subcutaneous dose is 125 mg weekly, and the mean terminal half-time is 13.1 days and 14.3 days, respectively [24]. This immunomodulator has probed efficacy in patients with PsA that did not respond to the DMARD with a significant effect in the progression of enthesitis and dactylitis. Further, patients with TNFi naisve and elevated CRP levels obtained a more substantial response. Nevertheless, it is not recommended for moderate to severe skin involvement or active axial disease [25,26]. The principal adverse effect studied associated with

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the use of abatacept is infections (Pneumonia, bronchitis, and UTI are the most common) with a cumulative incidence of 2.87 severe infections per 100 patient-years [24,26]. Tuberculosis screening before starting treatment is recommended as in similar treatments, but there is no established increase in incidence with abatacept [24]. There are records of one case of Pneumocystis jirovecii recorded in the 2017 ASTREA study in a patient with previous risk factors. Also, it can worsen symptoms in patients with chronic obstructive pulmonary disease (COPD) [24,26]. It has no established carcinogenic or teratogenic effect, but there is a reported slight statistically significant increase in cancer incidence compared to other bDMARDs [27]. On the other hand, this agent is suggested in patients with chronic heart failure because it improves insulin resistance and vascular dysfunction. In addition, it has an optimal profile in patients with demyelinating disorders [24].

Tofacitinib

Tofacitinib is an oral drug that inhibits the Janus kinase (JAK) enzyme, mainly JAK1/3, which has been identified as a therapeutic target for conditions with an exaggerated immune response. Tofacitinib excerpts an effect over the signal transducer and activator of the transcription (STAT) signaling cascade, which plays an important role in immune cell proliferation, cytotoxic attacks, and cell apoptosis. Its clearance is 70% hepatic and 30% renal, and it is metabolized mainly by CYP3A4 [28].

Tofacitinib is currently approved by the FDA for the treatment of moderate-severe rheumatoid arthritis, with a dose of 5 mg orally twice daily or 11 mg once daily in its extended-release presentation. In addition, since December 2017, the FDA has approved it for treating psoriatic arthritis with this same treatment regimen [28]. Its efficacy in pivotal clinical trials ranges from 39.9% to 69.6%, and its long-term effect has been maintained for up to 24 months [29]. The main adverse effects caused by this drug include nasopharyngitis and upper respiratory tract infections, headache, diarrhea, nausea, and vomiting. However, less common adverse effects have been reported, such as herpes zoster virus infection, malignancies such as skin cancer, and cardiovascular events [28,29].

Risankizumab

Risankizumab is a novel humanized IgG1 monoclonal antibody indicated for active psoriatic arthritis, moderate-to-severe plaque psoriasis, and active Crohn's disease [30]. This novel humanized monoclonal antibody inhibits the release of proinflammatory cytokines and chemokines by binding selectively to the p19 subunit of human interleukin 23 (IL-23) cytokine, inhibiting its interaction with the IL-23 receptor [31]. Risankizumab is administered via single-dose prefilled pen 150 mg subcutaneously at week 0, week 4, and every 12 weeks after that for both plaque psoriasis and psoriatic arthritis [30]. Among the most common adverse effects reported in people treated for plaque psoriasis and psoriatic arthritis included upper respiratory infections (>10%) and less commonly (1-10%) headaches, tiredness, injection site reactions, and fungal skin infections [32-34]. Risankizumab is safe overall and only contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab or any excipients and patients with active TB. Moreover, active monitoring for signs and symptoms of active TB during risankizumab treatment is recommended, as well as avoiding live vaccines and initiating therapy in patients with clinically meaningful active infections [32]. The British Society for Rheumatology (BSR) supported the benefits of risakinuzumab in patients with active PsA who had previous inadequate response/intolerance to one or more conventional synthetic DMARDs in response to the findings reported on both global phase 3 multicenter trials evaluating the efficacy and safety for risankizumab, KEEPsAKE 1 and the open-label extension KEEPsAKE 2 study [33,34].

Conclusion

Psoriatic arthritis is a common, disabling, rheumatic condition with multiple musculoskeletal and dermatological manifestations. Often, it is difficult to diagnose and treat because it mimics other inflammatory conditions and may be resistant to conventional treatments. While the efficacy of traditional disease-modifying drugs is fair, new biologic agents are proven to be useful for the majority of associated symptoms. Since PsA is associated with multiple comorbidities (i.e., obesity, metabolic syndrome, diabetes, hypertension, hyperlipidemia, fatty liver disease, and cardiovascular outcomes), special care should be taken in selecting the most suitable biologic treatment. In recent years, targeted biological medicines have changed the treatment scenario for this chronic inflammatory condition. However, large-scale prospective studies are still required to assess the different treatment strategies in order to improve the outcomes of patients with psoriatic arthritis.

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