

Impact of biologic therapy on the management of moderate to severe psoriasis: a systematic review

Impacto da terapia biológica no manejo da psoríase moderada a grave: uma revisão sistemática

Impacto de la terapia biológica en el tratamiento de la psoriasis moderada a grave: una revisión sistemática

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REVISA

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RESUMO

Objetivo: Avaliar o impacto da terapia biológica no tratamento da psoríase moderada a grave. **Métodos:** Uma revisão sistemática, baseada em dados do PubMed de janeiro de 2014 até agosto de 2024. Os artigos foram escolhidos de acordo com o tipo de estudo, intervenção, resultados e idiomas. Assim, foram selecionados 12 artigos entre os 53 com direcionamento na eficácia e segurança das imunoterapias no tratamento de pacientes com psoríase moderada a grave, por mais de um pesquisador, com base no título, resumo e texto completo. **Resultados:** Os artigos tiveram como resultado principal as taxas de resposta PASI (Índice de Área e Gravidade da Psoríase) e a qualidade de vida dos pacientes, no qual foi medido pelo DLQI. Destacando-se entre as pesquisas, os medicamentos, ixekizumab e brodalumab, os quais demonstraram alta eficiência. **Conclusão:** A revisão destaca que as terapias biológicas, particularmente Brodalumab e Ixekizumab, são altamente eficazes para psoríase moderada a grave, demonstrando respostas rápidas. Já o Brodalumab é superior na limpeza da pele, enquanto o Ixekizumab proporciona mais rapidez. Secukinumab e Ustekinumab também são benéficos, mas menos consistentes. Essas terapias representam avanços significativos, melhorando desfechos clínicos e qualidade de vida, e devem ser escolhidas com base na individualidade do paciente, eficácia e segurança.

Descritores: Terapia Biológica; Psoríase; Qualidade de Vida; Biológica.

ABSTRACT

Objective: To evaluate the impact of biological therapy in the treatment of moderate to severe psoriasis. **Methods:** A systematic review based on PubMed data from January 2014 to August 2024. Articles were selected according to study type, intervention, outcomes, and language. Thus, 12 articles were chosen from the 53 that focused on the efficacy and safety of immunotherapies in the treatment of patients with moderate to severe psoriasis. The selection was conducted by more than one researcher, based on the title, abstract, and full text. **Results:** The main outcomes of the articles were PASI (Psoriasis Area and Severity Index) response rates and patients' quality of life, measured by the DLQI. Among the studies, ixekizumab and brodalumab stood out as highly effective treatments. **Conclusion:** The review highlights that biological therapies, particularly Brodalumab and Ixekizumab, are highly effective for moderate to severe psoriasis, showing rapid responses. Brodalumab is superior in skin clearance, while Ixekizumab provides faster results. Secukinumab and Ustekinumab are also beneficial but less consistent. These therapies represent significant advances, improving clinical outcomes and quality of life, and should be chosen based on patient individuality, efficacy, and safety.

Descriptors: Biological Therapy; Psoriasis; Quality Of Life; Biologics.

RESUMEN

Objetivo: Evaluar el impacto de la terapia biológica en el tratamiento de la psoriasis moderada a grave. **Métodos:** Revisión sistemática basada en datos de PubMed desde enero de 2014 hasta agosto de 2024. Los artículos fueron seleccionados según el tipo de estudio, intervención, resultados e idioma. Así, se eligieron 12 artículos de los 53 que abordaban la eficacia y seguridad de las inmunoterapias en el tratamiento de pacientes con psoriasis moderada a grave. La selección fue realizada por más de un investigador, basándose en el título, resumen y texto completo. **Resultados:** Los principales resultados de los artículos fueron las tasas de respuesta PASI (Índice de Área y Severidad de la Psoriasis) y la calidad de vida de los pacientes, medida mediante el DLQI. Entre los estudios, ixekizumab y brodalumab destacaron por su alta eficacia. **Conclusión:** La revisión destaca que las terapias biológicas, particularmente Brodalumab e Ixekizumab, son altamente eficaces para la psoriasis moderada a grave, mostrando respuestas rápidas. Brodalumab es superior en la limpieza de la piel, mientras que Ixekizumab ofrece resultados más rápidos. Secukinumab y Ustekinumab también son beneficiosos, pero menos consistentes. Estas terapias representan avances significativos, mejorando los resultados clínicos y la calidad de vida, y deben elegirse en función de la individualidad del paciente, la eficacia y la seguridad.

Descriptores: Terapia Biológica; Psoriasis; Calidad de vida; Biológico.

REVIEW

Introduction

Psoriasis is an inflammatory disease, which affects about 2% of the population. It has a lower prevalence in the Asian and African population and about 11% in Caucasians and Scandinavians⁽¹⁾. This pathology has a strong genetic component and is related to nine genomic susceptible regions and to HLA-C 06:02, which is the allele most related to susceptibility, reaction to treatments, disease severity, comorbidity and phenotypic characteristics of the disease⁽²⁾. Its pathophysiology is due to an inflammation that promotes the uncontrolled proliferation of keratinocytes and their dysfunctional differentiation. Antigen-presenting dendritic cells play an important role in the early phase of the disease, recognizing antimicrobial peptides (PAMs) secreted by keratinocytes in response to injury (prevalent in this pathology)⁽²⁾. The most common PAMs are LL37, β defensins and S100 proteins. This interaction can generate 4 forms of clinical presentation.

Psoriasis vulgaris has demarcated, erythematous, pruritic plaques covered with silvery scales, which may occur most commonly on the trunk, scalp, and surface of the limbs. Inverse psoriasis affects the fold regions and is characterized by erythematous and slightly erosive plaques and spots. Guttate psoriasis is an acute-onset variant with small erythematous plaques and usually affects children and adolescents. It can arise after infections of the tonsils by group A streptococci and about 1/3 of patients with this type of psoriasis will develop plaque psoriasis in their adult life. Pustular psoriasis, on the other hand, can be localized or generalized. The latter presents with an acute and rapidly progressive condition characterized by diffuse redness and subcorneal pustule and may present systemic symptoms, being considered the most severe version of the disease⁽¹⁾.

As it is a chronic disease, it needs long-term treatment, and the choice of this is made according to the severity of the disease, comorbidities and access to medical care. Patients are divided into mild or moderate to severe disease, according to the clinical severity of the lesions and the percentage of body affected (PASI) and the patient's quality of life. The mild to moderate version is treated with glucocorticoids, vitamin D analogues and phototherapy. Moderate to severe treatment requires systemic treatment; small molecules or biological therapies, whose impact will be investigated through this research.

In this sense, the objective of this research was to demonstrate the impact of biological therapy on the management of moderate to severe psoriasis.

Methodology

Database

The study is a systematic review carried out by a survey of studies indexed in the PubMed database, published between January 2014 and August 2024. The search strategy used in English was the following descriptors: (psoriasis) AND (moderate) AND (severe) AND (biological therapy) AND (quality of life) AND (biologics) OR (non-biological therapy) NOT (pediatric). The filters used were: Clinical Trial, Meta-Analysis, Randomized Controlled Trial, Systematic Review, in the last 10 years, English, Portuguese.

Inclusion and exclusion criteria

Studies in adults over 18 years of age diagnosed with moderate to severe psoriasis with exposure to biologic therapy treatment compared with other treatments were included. The outcome of interest selected was the reduction of reddish spots and whitish scales, characteristic of psoriasis.

Articles that were not related to the topic were excluded, studies with diagnoses of mild psoriasis, studies in pediatric populations, animal studies, not written in Portuguese or English, had only the available abstract, reviews, letters to the editor, opinions, and case studies, which were not published between 2014 and 2024.

Selection of studies

The selection of articles took place in August 2024 and was carried out by two reviewers, independently, analyzing the titles and abstracts potentially eligible for inclusion in this review. All disagreements were resolved by consensus.

A total of 53 articles were found at first, and after the first analysis, 17 articles were selected based on titles and abstracts, using the aforementioned exclusion criteria. In this way, the reviewers evaluated the articles in their entirety and extracted the necessary data on authors, year of publication, participants' characteristics, interventions, outcomes, and main outcomes. With this last evaluation of the texts in full, 13 articles were selected for the systematic review.

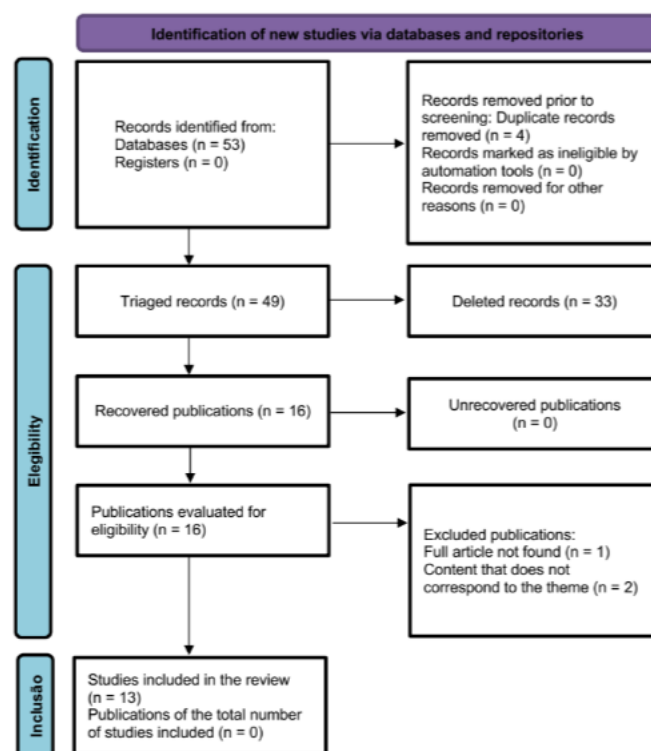


Figure 1 - Article exclusion flowchart.

Results

A total of 53 articles were selected and, based on the inclusion and exclusion criteria, 12 articles were highlighted for review. The reviewed studies provide a detailed overview of the efficacy and safety of various biologic therapies for the treatment of moderate to severe psoriasis, focusing on outcomes such as the Psoriasis Area and Severity Index (PASI) and patients' quality of life. In the study by Prinsen et al., the impact of an intervention related to quality of life during biological treatment was evaluated. Although there was no significant additional effect on patients' quality of life, as measured by the DLQI, the intervention improved the discussion of health-related aspects of quality of life (HRQoL) between physicians and patients. In addition, both patients and dermatologists reported greater satisfaction with the care process^[14].

Gottlieb et al. investigated the efficacy of Certolizumab pegol in two phase 3 studies (CIMPASI-1 and CIMPASI-2)[13]. Primary outcomes included PASI 75 and PGA 0/1 response rates (defined as "clear" or "almost clear"). At week 16, PASI 100 response rates were 12.7% for the 400 mg dose and 13.7% for the 200 mg dose. These rates increased to 23.6% and 21.8%, respectively, at week 48, demonstrating sustained efficacy over time. The results also indicated improvements in quality of life, as measured by the DLQI, especially between weeks 16 and 48.

Nakagawa et al. evaluated Brodalumab in a Japanese population with moderate to severe psoriasis. The results showed that among the three doses tested (70 mg, 140 mg, and 210 mg), the 210 mg dose resulted in the greatest improvement in PASI, with 96.8% of patients achieving PASI 75^[12]. In addition,

there were notable improvements in the Investigator's Global Assessment (sPGA), with many patients achieving "no injury" or "near no injury" levels. The study also reported improvements in quality of life and significant reduction in body areas affected by psoriasis, particularly the nails and scalp.

In the comparative study by Elewski et al., Secukinumab was compared to Ustekinumab in terms of efficacy in eliminating skin lesions. Secukinumab demonstrated superiority, with a higher number of patients achieving PASI 90-100 responses at week 12, which translated into significant improvements in quality of life, as measured by the DLQI[11]. Notably, patients who achieved PASI 100 had a more rapid improvement in quality of life, with most reporting minimal impacts of psoriasis within the first few weeks of treatment.

Papp et al. performed an integrated analysis of the AMAGINE-2 and AMAGINE-3 trials, which compared Brodalumab with Ustekinumab in patients with moderate to severe psoriasis. The results showed that Brodalumab had improved PASI 75, 90, and 100 response rates, with 85.7% of patients achieving PASI 75 and 40.5% achieving PASI 100 at week 12^[10]. The results were consistent for both patients who had previously used biologic therapies and those without prior treatment, suggesting the efficacy of brodalumab in diverse patient populations.

Xu et al. conducted a meta-analysis comparing 13 biologic therapies for psoriasis. The analysis identified Brodalumab, Briakinumab, and Infliximab as the most effective drugs, with better outcomes at PASI 75, 90, and 100. Brodalumab, specifically, was highlighted as superior in achieving PASI 90 and 100.^[9] The study also looked at the safety of the therapies, indicating that most biologics had a higher incidence of adverse effects compared to placebo, especially headaches and infections, although the efficacy outweighed these risks in many cases.

Sator et al. explored the use of adalimumab in patients who switched from other biologics. The results showed a continuous improvement in psoriasis severity and quality of life over 52 weeks. At week 4, about 50% of patients achieved PASI 50, and at week 52, 42.3% of patients achieved PASI 100^[8]. The study also indicated that the combination of Adalimumab with topical treatments, such as Calcipotriol and Betamethasone, was effective in the initial phase, but its effects were not maintained after 8 weeks, suggesting the need for adjustments in the long-term treatment strategy.

Leonardi et al. compared the efficacy of different biologics and observed that Brodalumab and Ixekizumab had the highest PASI 90 and 100 response rates in the first weeks of treatment. At week 16, Ixekizumab was shown to be more effective at achieving PASI 90/100, while Brodalumab stood out at week 12 for PASI 100^[7]. These results indicate that these therapies are highly preferable for patients seeking a rapid and complete response in the treatment of psoriasis.

Chiricozzi et al. conducted a real-world study on Secukinumab, demonstrating a significant reduction in PASI after 52 weeks, especially in bio-naïve patients. Bio-naïve patients, who were generally younger and had a lower body mass index (BMI), responded better to treatment, with the mean PASI dropping from 16.65 at baseline to 1.57 after 52 weeks^[6]. This result suggests that patient profile may influence the efficacy of secukinumab treatment.

Kokolakis et al. investigated the efficacy of Bimekizumab in patients who switched from Adalimumab, Ustekinumab, or Secukinumab. Switching to Bimekizumab resulted in high PASI 90 and 100 response rates, with rapid and sustained responses for up to 80 weeks. Treatment was well tolerated, with most adverse events being mild or moderate, and no significant new safety findings after switching, suggesting that bimekizumab is a viable and safe option for the management of moderate to severe plaque psoriasis [5].

Finally, Langley et al. showed that switching from Ustekinumab to Guselkumab in patients with inadequate response resulted in significant improvements in PASI 90 and 100 response rates, especially at weeks 28 to 40. At week 52, 36.3% of patients in the Guselkumab group achieved PASI 100, compared to 17.3% in the Ustekinumab group, demonstrating the superiority of Guselkumab. In addition, the meta-analysis by Sbidian et al. corroborated these findings, showing that the anti-IL17, anti-IL23, and anti-TNF-alpha agents were the most effective, with Infliximab and Bimekizumab standing out in terms of efficacy and safety [4].

Such studies provide solid evidence on the efficacy and safety of biologic therapies in the treatment of moderate to severe psoriasis. Brodalumab and Ixekizumab are highlighted as highly effective biological agents in the treatment of moderate to severe psoriasis. Brodalumab has shown high response rates, especially in achieving PASI 90 and PASI 100, standing out as one of the best options. Ixekizumab stood out for its rapid efficacy in the first few weeks, while Secukinumab outperformed Ustekinumab in eliminating skin lesions and improving quality of life. Together, these three agents are powerful therapeutic options for the management of psoriasis. These results highlight the relevance of these therapies in current clinical practice, offering viable and safe options to achieve the best possible outcomes in disease control [14].

Discussion

In the present review, 12 articles [3-14] were analyzed that investigated the impact of biologics in the treatment of moderate to severe psoriasis. Brodalumab and Ixekizumab are the agents that have shown the best efficacy in managing the disease. As highlighted in the results of the article, the first agent showed efficacy by reaching PASI 90 and 100, the Psoriasis Area Severity Index (PASI), which is used to classify skin lesions caused by psoriasis, stratification is made based on the severity and extent of the lesions, based on ectoscopy, that is, the global assessment at the patient's first assessment.

Psoriasis, an autoimmune disease usually developed before the age of 35, affects the compromised individual in a systemic way, and may be associated with metabolic, cardiovascular, arthritic and, above all, psychological dysfunctions[15], since it manifests itself on the skin in the form of scaly and reddish skin lesions, it is often seen with a stigmatizing look. Thus, while a cure has not yet been discovered, research is aimed at improving treatment and consequently the quality of life of patients.

Brodalumab is a human monoclonal antibody that blocks the action of IL-17A, IL-17F, IL-17A/F and IL-17E (or IL-25), by the analysis made in this article it was considered an effective treatment option, in relation to PASI 90-100 it obtained the best result, among briakinumab, infliximab and

ixekizumab^[9], it presented better efficacy in the treatment than ustekinumab^[10] and as ixekizumab lower NNT (number needed to treat)^[7], demonstrating the ability to achieve the main objective of the treatment, the complete cleansing of the skin. In addition, brodalumab was tested in Japanese patients, demonstrating 96.8% improvement in the group that received 210 mg concentration^[12].

The biologic secukinumab was analyzed by 4 of the 12 articles included in this review, with high-certainty evidence the agent was less efficient than infliximab, bimekizumab, ixekizumab and risankizumab^[3], in addition, it was inferred that the biologic bimekizumab was more effective than adalimumab, ustekinumab and secukinumab in terms of efficacy^[4]. However, secukinumab has shown positive results for bionative, younger patients with lower BMI and lower appearance of skin lesions^[6] and higher efficacy than Ustekinumab, which has been shown to clean the skin, PASI 90 - 100, 4 weeks faster than PASI 75 - 89^[11].

Biological therapy showed great promise according to the results presented in this article, evidencing the reach of PASI 75 and PASI 90. However, among the biologics analyzed, one of them did not show significant efficacy, ustekinumab was analyzed by 4 articles included in this review, according to the results the agent was less effective than bimekizumab in clinical trials, such as BE SURE, BE VIVID and BE RADIANT, less the latter having mild to moderate adverse events^[5], less efficient than brodalumab, Regardless of exposure to other biologic therapy^[10], lower sustained efficacy in skin cleansing through week 52 and better quality of life outcome than secukinumab^[11]. In addition, one article compared the change from the biological ustekinumab to guselkumab, demonstrating significant improvement in skin lesions^[4].

Most studies followed the evolution of patients at 52 weeks of treatment, however, some agents demonstrated efficacy up to 8 weeks, after which the effect was no longer observed. Adalimumab, an anti-TNF-alpha, was analyzed in two articles, and although it showed improvement in the quality of life of patients it was beneficial only in the first weeks^[8] and had lower performance than infliximab^[3], only one study considered adalimumab superior to other biological therapy, so this result should be observed with caution.

The present review had some limitations, such as the small number of articles faithfully related to the theme and the fact that only articles in English, Portuguese and Spanish were included. We sought to present alternatives in biological therapy for the treatment of lesions resulting from moderate to severe psoriasis, emphasizing that even though this disease affects a smaller percentage of the population, it deserves due attention to improve the quality of life of patients.

Conclusion

Analysis of studies on moderate to severe psoriasis demonstrates remarkable advances in treatment using biologic therapies for this complex condition. The data reveal that biological agents, especially Brodalumab and Ixekizumab, are particularly effective, showing rapid and prolonged responses,

with high rates of PASI 75 and PASI 100. Brodalumab, in particular, stood out for its high efficiency and the speed in achieving positive treatment results.

Ixekizumab is notable for its effectiveness, making it a valuable option for patients who require quick results. Although Secukinumab and Ustekinumab have also shown benefits, their results are less consistent. Secukinumab has shown good results in specific patients, while Ustekinumab has shown moderate performance relative to other biologics.

These biological therapies represent a significant advance in the treatment of moderate to severe psoriasis, offering important alternatives for patients who do not respond well to traditional options, in such a way that they improve both clinical outcomes and the quality of life of patients, these treatments highlight the importance of continuing to invest in research and innovation in dermatology.

Therefore, the selection of biological therapies must consider the individual efficacy of each drug, the safety profile, and the patient's response, to ensure the choice of the most effective and appropriate treatment for each individualized clinical situation.

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