Dermatology Reports
https://www.pagepress.org/journals/index.php/dr/index

eISSN 2036-7406

Please cite this article as:

D'Arino A, Fargnoli MC, Frascione P, et al. Efficacy and safety of risankizumab in patients with erythrodermic and sub-erythrodermic psoriasis: a case series. *Dermatol Rep 2025 [Epub Ahead of Print] doi: 10.4081/dr.2025.10379*

Submitted 31/03/25 - Accepted 08/06/25

Efficacy and safety of risankizumab in patients with erythrodermic and sub-erythrodermic psoriasis: a case series

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Key words: psoriasis; risankizumab; erythrodermic psoriasis; safety; efficacy.

Contributions: ADA, DO, study conception and design, manuscript drafting and editing; ADA, MCF, CA, AD, DG, VL, MM, FP, EV, DO, collection and interpretation of data. All authors have read and approved the final version of the manuscript and agreed to be accountable for all aspects of the work.

Conflict of interest: MCF has served on advisory boards and received honoraria for lectures and/or research grants from AMGEN, Almirall, Abbvie, Boehringer Ingelheim, BMS, Galderma, Kyowa Kyrin, Incyte, LEO Pharma, Pierre Fabre, UCB, Lilly, Pfizer, Janssen, MSD, Novartis, Sanofi, Regeneron, Sun Pharma; AD has served as a speaker, consultant, or advisory board member for Abbvie, Almirall, Amgen, Eli Lilly, Leo Pharma, Janssen, Novartis, Boehringer Ingelheim, and UCB Pharma outside the submitted work; MM acted as a speaker or consultant for Abbvie, Almirall, Amgen, LeoPharma, UCB pharma, Eli Lilly, Novartis, Janssen, Bristol-Meyer-Squibb and Boehringer Ingelheim; DO has been a speaker and/or consultant for Abbvie, Almirall, LeoPharma, UCB-pharma, Bristol-Meyer-Squibb, and Boehringer Ingelheim outside the submitted work. The other authors have no conflict of interest to declare.

Ethics approval and consent to participate: institutional review board approval was exempted for this study as its procedure did not deviate from good routine clinical practice. The study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments. All patients gave written informed consent for the retrospective retrieval of anonymized data.

Consent for publication: patients provided written consent to use their personal data for the publication of this case report and any accompanying images.

Availability of data and materials: additional data supporting the findings of this study are available from the corresponding author on reasonable request.

Abstract

Erythrodermic psoriasis (EP) is a severe and complex form of psoriasis. While risankizumab, an interleukin (IL)-23 inhibitor, has demonstrated efficacy in patients with moderate-to-severe plaque psoriasis, its effectiveness in patients with EP remains less explored. The literature contains several small studies and case reports that provide evidence for the potential use of biologic therapies in the treatment of erythrodermic psoriasis. This case series suggests that risankizumab may represent an effective and sustainable treatment option for patients with a history of EP.

Introduction

Erythrodermic psoriasis (EP) is a severe psoriasis form characterized by extensive erythema involving more than 75 percent of the body surface area (BSA), and it can present as either acute or chronic. EP is generally accompanied by diffuse desquamation and, in some cases, systemic symptoms, which can be life-threatening. The approach to management is primarily based on smaller studies, and a consensus is still lacking. Currently, cyclosporine or infliximab are considered possible first-line therapies according to National Psoriasis Foundation Consensus guidelines. In the literature, there are several small studies and case reports providing evidence on the possible use of biologics for the treatment of EP. The majority have been focused on interleukin (IL)-17 inhibitors, due to their rapid onset of action. Here we report a case series comprising six cases of EP successfully treated with risankizumab, an inhibitor of the p19 subunit of IL-23.[1]

Case Series

Case 1

A 54-year-old male with a long history of plaque psoriasis and multiple comorbidities (hypertension and excessive alcohol use) was referred due to a worsening of his psoriasis for one year. He had been previously treated with topical drugs and phototherapy, with only partial improvements. On physical examination, the patient presented a diffuse cutaneous redness with a BSA of 85% (Figure 1a), a Psoriasis Area and Severity Index (PASI) score of 30, and a Dermatology Life Quality Index (DLQI) of 20. In the absence of contraindications, following screening, risankizumab was started at standard dosage. During the first follow-up visit after 4 weeks, the PASI score decreased to 7, and the BSA decreased to 20%. At week 16, we obtained complete disease remission with PASI 0 (Figure 1b) and no impact on quality of life (DLQI 0).

Case 2

A 52-year-old male patient presented with a severe, diffuse skin rash characterized by erythema and desquamation involving the entire body. His family history was positive for psoriasis. The patient was under several medications due to a history of depression, psychosis, and alcoholism, notably lorazepam, sodium valproate, olanzapine, and sertraline. His past medical history was otherwise unremarkable, with the exception of several traumatic bone fractures. Histological examination confirmed the diagnosis of EP with a PASI score of 50, a BSA of 90% (Figure 1c), and a DLQI of 29. In the absence of contraindications following screening, the patient was thus started on risankizumab at standard dosage. During the first follow-up visit after 4 weeks, the blood tests had normalized, the PASI score decreased to 10, and the BSA decreased to 25%. At week 16, we obtained complete disease remission with PASI 0 (Figure 1d) and no impact on quality of life (DLQI 0).

Case 3

A 30-year-old male smoker was admitted to our dermatology outpatient department for the presence of diffuse erythematous scaly plaques. The patient suffered from plaque psoriasis for 6 years, while his medical history was otherwise unremarkable. On physical examination, widespread erythema and desquamation involved most of the body, including the face, the scalp, and the genital region. The PASI score was 36, the BSA was 75% (Figure 2a), and the DLQI was 27. Screening blood tests showed elevated WBC (16,800/μL) with neutrophilia (12,800/μL) and high uric acid (480). Infectious disease screening was negative for hepatitis B virus, hepatitis C virus, HIV, and tuberculosis. The patient was started on risankizumab at the standard dosage protocol. After 4 weeks, the patient already exhibited significant clinical improvement with a reduction in PASI score to 6 and a BSA of 14%. At week 16, there was complete remission of the disease (Figure 2b) with PASI and DLQI scores of 0 and normalization of blood parameters. The patient is still in complete remission after 52 weeks of follow-up, and no adverse effects have been reported.

Case 4

A 21-year-old otherwise healthy male patient, with severe plaque psoriasis for 6 years without psoriatic arthritis, was referred to the outpatient department due to a rebound after the self-administration of oral steroids. He failed therapy with methotrexate (10 mg per week). Adalimumab 40 mg every 2 weeks was administered without any improvement. Only partial results were obtained with ustekinumab 45 mg every 12 weeks. The patient presented with severe EP, a BSA of 80%, a PASI score of 40 (Figure 2c), and a DLQI of 24. Risankizumab was initiated at the labeled dosage, and at week 4, there was a significant clinical improvement: the PASI score decreased to 12, and BSA

involvement decreased to 55%. At week 16, we obtained complete disease resolution with PASI 0 (Figure 2d) and no impact on quality of life (DLQI 0). At the 52-week follow-up, the patient maintained the remission with no adverse events.

Case 5

A 57-year-old male patient with a 21-year history of plaque psoriasis was referred to the outpatient department due to a sudden worsening of the clinical lesions. The patient was undergoing treatment with narrowband UVB (nbUVB) phototherapy three times a week, with a good clinical response. During physical examination, the patient showed diffuse suberythroderma (Figure 3a) involving almost the entire body, including difficult-to-treat areas, specifically the face, the scalp, the genitals, and all 20 nails. The PASI score was 44, and the DLQI was 20. After receiving screening tests, which came back negative, the patient was promptly started on risankizumab 150 mg with standard treatment protocol. During the first follow-up visit at week 4, the patient had already significantly improved, and the PASI score had reduced to 9, with a DLQI of 2. At week 16, the patient showed complete disappearance of the skin lesions (Figure 3b), with a PASI and DLQI score of 0. At week 40, the patient manifested sustained disease improvement, with PASI and DLQI scores of 0. The patient is still undergoing treatment with risankizumab and has shown no adverse events or relapses to date.

Case 6

A 77-year-old female patient with multiple comorbidities (hypertension, obesity, and dyslipidemia), previously treated in another hospital with tralokinumab for suspected atopic dermatitis, presented to our outpatient department complaining of the sudden worsening of her dermatologic condition. We made a clinical-pathological diagnosis of EP with a BSA involvement of 90% (Figure 3c), a PASI score of 35, and a severe impact on quality of life (DLQI 22). In the absence of contraindications following screening, risankizumab was initiated at the labeled dosage, and at week 4, there was a significant clinical improvement with a PASI score of 10 and a BSA involvement of 40%. At week 16, we obtained complete disease resolution (Figure 3d) with PASI 0 and DLQI 0.

Discussion

EP is a severe psoriasis subtype characterized by widespread erythema and desquamation. Recognition and treatment of EP is of the utmost importance to prevent possible life-threatening complications, such as cardiac failure, shock, acute renal failure, and infections.[2,3] The need for rapidly acting therapies has led to the recommendation of cyclosporine or infliximab in the National

Psoriasis Foundation Consensus guidelines.[4] Moreover, most of the literature has focused on IL-17 inhibitors, such as secukinumab and ixekizumab, given their rapid onset of action.[5] In a recent systematic review,[6] ustekinumab and infliximab have been reported as the most used drugs, while secukinumab was recommended as a second-line agent.

Risankizumab is a fully human monoclonal IgG that inhibits the p19 subunit of IL-23.[7,8] It received Food and Drug Administration (FDA) approval for the treatment of moderate to severe psoriasis in 2019.[9] In the literature, only a few case reports have reported the successful treatment of EP patients with risankizumab.[10,11] Orsini *et al.*, in a recent retrospective study, confirmed the efficacy of risankizumab on patients affected by very severe psoriasis in a real-life setting, also with the involvement of difficult-to-treat areas.[12]

The results of our case series highlight the efficacy of risankizumab in the treatment of this debilitating condition. All treated patients showed significant clinical improvement, with complete remission of the disease within 16 weeks. Furthermore, the reduction in DLQI scores suggests a clinically meaningful impact on quality of life. Risankizumab was well tolerated by patients, and no significant adverse effects were reported during the treatment. Finally, the efficacy seems to be long-lasting with a maintained response.

Certainly, this case series has some limitations. First, the analysis of clinical efficacy and safety data is statistically weak due to the lack of a control group. Second, the follow-up period is short, and the sample size is small. Lastly, the interventions were not carried out in a double-blind scenario.

Conclusions

It is crucial to continue collecting clinical data and conducting larger studies to establish standardized treatment protocols and optimize the management of this complex disease. Nevertheless, these clinical responses appear promising and warrant further investigations, such as larger clinical trials, which could ultimately lead to the inclusion of risankizumab in the guidelines for the treatment of EP.

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Figure 1. a) Extensive erythema with diffuse desquamation (BSA of 85%, PASI: 30); **b**) complete disease remission (PASI 0); **c**) severe, diffuse skin rash characterized by erythema and desquamation involving all the body (BSA of 90%, PASI: 50); **d**) complete disease remission (PASI 0).

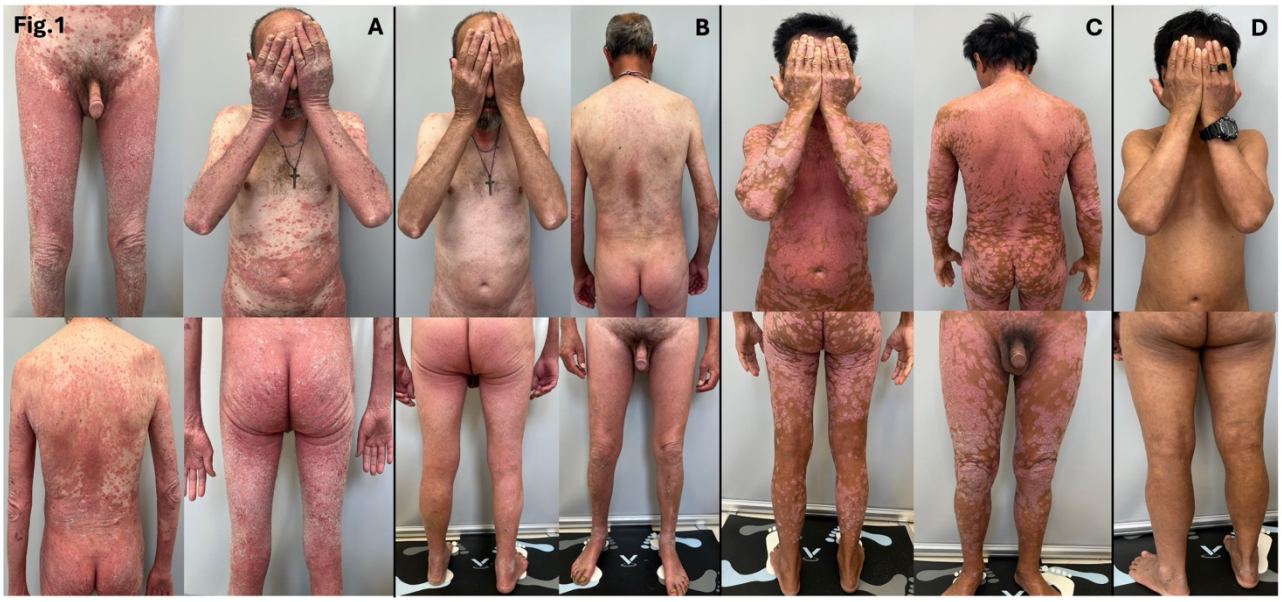

Figure 2. a) Widespread erythema and desquamation involved most of the body, including the face, the scalp, and the genital region (BSA of 75%, PASI: 36); **b**) complete disease remission (PASI 0); **c**) severe, diffuse skin rash characterized by erythema and desquamation (BSA of 80%, PASI: 40); **d**) complete disease remission (PASI 0).

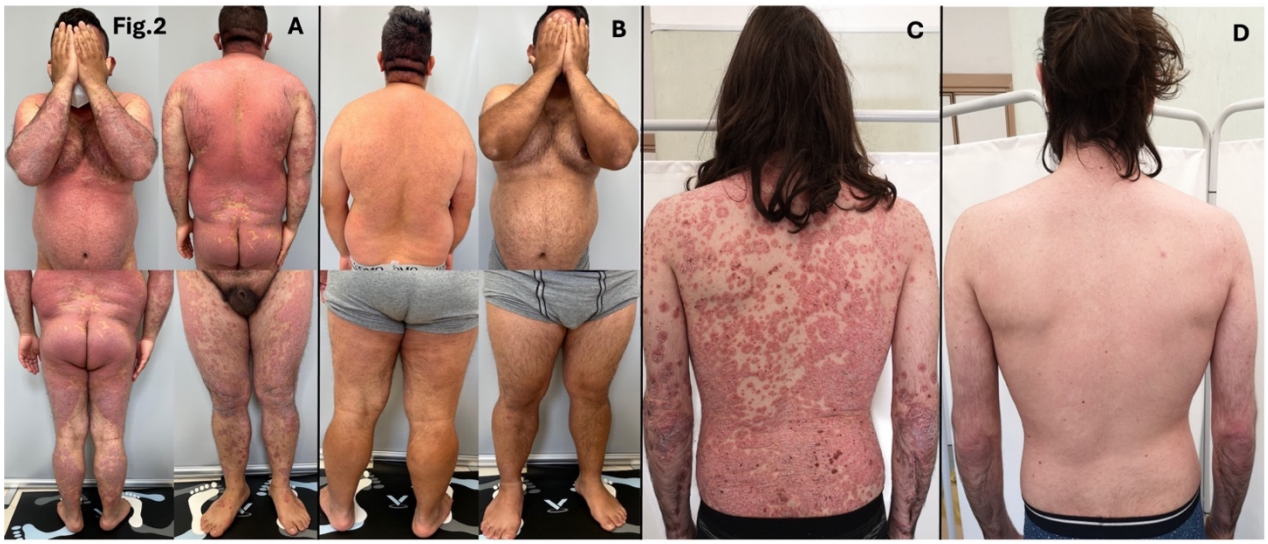

Figure 3. a) Diffuse sub erythroderma involving almost the entire body, including difficult-to-treat areas, specifically the face, the scalp, and the genitals (PASI: 44); **b**) complete disease remission (PASI 0); **c**) severe, diffuse skin rash characterized by erythema and desquamation (BSA of 90%, PASI: 35); **d**) complete disease remission (PASI 0).