

# Real-world efficacy and safety of risankizumab in moderate-to-severe psoriasis: experience from a tertiary center

## Eficácia e segurança do risankizumab na psoríase moderada a grave: estudo de coorte retrospectivo num centro terciário português

Ana Ferreira<sup>1,2,3\*</sup>, Clara Valente<sup>1,3</sup>, Inês Aparício-Martins<sup>1,3</sup>, Maria J. Paiva-Lopes<sup>1,2,3</sup>,  
Joana Cabete<sup>1,2,3</sup>, and Ana L. João<sup>1,3</sup>

<sup>1</sup>Department of Dermatology and Venereology, Hospital de Santo António dos Capuchos, Unidade Local de Saúde São José; <sup>2</sup>Department of Dermatology and Venereology, NOVA Medical School, Faculdade de Ciências Médicas; <sup>3</sup>Centro Clínico Académico de Lisboa. Lisboa, Portugal

### Abstract

**Objectives:** To assess the real-world effectiveness and safety of risankizumab in patients with moderate-to-severe psoriasis, including special area involvement. **Methods:** A retrospective cohort study was conducted in a Portuguese tertiary hospital, including adult patients with moderate-to-severe psoriasis treated with risankizumab for at least 16 weeks. Clinical assessments were performed at weeks 16 and  $\geq 52$ . Efficacy was measured by PASI-75, PASI-90, and PASI-100 responses. Safety was evaluated based on reported adverse events (AE) and treatment discontinuations. **Results:** A total of 114 patients were included, 63.2% male, with a median age of 50 years and a median disease duration of 16 years. The median number of comorbidities per patient was 2. At week 16, PASI-90 and PASI-100 were achieved by 71.3% and 61.4%, respectively. At  $\geq 52$  weeks, PASI-90 was achieved by 86.6% and PASI-100 by 79.4%. Complete resolution was observed in 95.2% of scalp psoriasis, 88.5% of nail psoriasis, and 54.5% of palmoplantar psoriasis cases. Psoriatic arthritis resolved completely in 67.7% of cases. Three malignancies were reported without an established causal relationship to risankizumab. Overall, 12.3% discontinued treatment, most due to primary or secondary efficacy failure. No other AEs were reported. **Conclusion:** Risankizumab demonstrated high effectiveness and a favorable safety profile in a real-world setting, with robust short- and long-term outcomes, including in special areas and psoriatic arthritis. These findings support its use in routine clinical practice. Further real-world studies with comparators are warranted.

**Keywords:** Psoriasis. Risankizumab. Interleukin-23. Real-world evidence. Biologics. Psoriatic arthritis.

### Resumo

**Objetivo:** Avaliar a eficácia e segurança do risankizumab na prática clínica em doentes com psoríase moderada a grave, incluindo envolvimento de áreas difíceis de tratar. **Método:** Estudo de coorte retrospectivo realizado num hospital terciário português, incluindo doentes adultos com psoríase moderada a grave tratados com risankizumab durante pelo menos 16 semanas. A eficácia foi avaliada com base nas respostas PASI-75, PASI-90 e PASI-100 nas semanas 16 e  $\geq 52$ . A segurança foi analisada com base em eventos adversos e descontinuações. **Resultados:** Foram incluídos 114 doentes, 63.2% do sexo masculino, com idade mediana de 50 anos e duração mediana da doença de 16 anos. A mediana de comorbilidades por doente foi 2. Na semana 16, 71.3% atingiram PASI-90 e 61.4% PASI-100. Na semana  $\geq 52$ , 86.6% atingiram PASI-90 e 79.4% PASI-100.

#### \*Correspondence:

Ana Ferreira  
E-mail: [anafcferreira@gmail.com](mailto:anafcferreira@gmail.com)  
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Observou-se resolução completa em 95.2% dos casos de psoríase do couro cabeludo, 88.5% da psoríase ungueal e 54.5% da psoríase palmoplantar. A artrite psoriática teve resolução completa em 67.7%. Três casos de neoplasia foram diagnosticados sem relação causal estabelecida com o fármaco. 12.3% descontinuaram o tratamento, principalmente por falência primária ou secundária. Nenhum outro evento adverso foi reportado. **Conclusões:** O risankizumab demonstrou elevada eficácia e um perfil de segurança favorável na prática clínica, com benefícios sustentados a curto e longo prazo, inclusive em áreas difíceis de tratar. Contudo, são necessários mais estudos de dados de vida real com comparadores.

**Palavras-chave:** Psoríase. Risankizumab. IL-23. Dados de vida real. Biológicos. Artrite psoriática.

## Introduction

Moderate-to-severe plaque psoriasis is a chronic immune-mediated skin disease that significantly impairs quality of life<sup>1</sup>. The advent of biologic therapies has transformed disease management, allowing patients to achieve high levels of skin clearance, such as PASI-90 and PASI-100.

Risankizumab is a humanized IgG1 monoclonal antibody targeting the p19 subunit of interleukin-23 (IL-23), a key cytokine involved in the differentiation and maintenance of Th17 cells, which play a central role in the pathogenesis of psoriasis<sup>1</sup>. While IL-17 inhibitors often demonstrate rapid onset of action and high short-term efficacy, IL-23 inhibitors tend to provide superior durability of response<sup>2</sup>, with better drug survival rates<sup>3</sup>. Moreover, selective inhibition of IL-23 preserves IL-17 cells that are independent of IL-23 and important for mucocutaneous immunity, potentially offering a better safety profile compared to direct IL-17 blockade<sup>4</sup>.

Regarding randomized controlled trials (RCTs), risankizumab has been established as a safe and effective treatment for moderate-to-severe plaque psoriasis, with superior efficacy compared to ustekinumab, secukinumab, and adalimumab, in achieving PASI-90 and PASI-100<sup>5-7</sup>. However, its long-term performance in routine clinical practice remains underexplored. Real-world studies are essential to evaluate treatment outcomes in more complex patients, often excluded from RCTs, including those with multiple comorbidities and prior biologic exposure.

## Methods

To address this gap, we conducted a retrospective cohort study in a tertiary hospital to evaluate the real-world outcomes of risankizumab in adult patients with moderate-to-severe psoriasis. Patients included had received risankizumab for at least 16 weeks and

underwent clinical assessments at 16 and  $\geq 52$  weeks. Efficacy was determined by PASI reduction, while safety was assessed through reported adverse events (AEs). Data analysis was performed using Excel, with descriptive statistics used to summarize demographic and clinical data. Proportions were expressed as percentages, and continuous variables were presented as medians with ranges. This study was conducted in accordance with the ethical principles of the Declaration of Helsinki. Patient confidentiality was maintained throughout the study, and all data were anonymized before analysis.

A total of 114 patients were included in the study, of whom 63.2% were male, with a median age of 50 years (range: 18-82). The median number of comorbidities per patient was 2, with the most common being dyslipidemia (44.7%), arterial hypertension (40.4%), obesity (25.4%), and psychiatric disorders (25.4%). Notably, 18.0% had a history of treated latent tuberculosis, and 6.1% had a present or previous history of malignancy. The median disease duration was 16 years (range: 1-73). Psoriatic arthritis was present in 27.2% of patients (31/114). Special area involvement was observed in 61.4% of patients (70/114), with the scalp being the most frequently affected site (26.8%), followed by the nails (22.8%) and the palmoplantar regions (9.6%). No cases of genital psoriasis were recorded in this cohort (Table 1).

In this cohort, 43.0% of patients (49/114) were biologic-naïve, while the remaining had previously failed a mean of 0.84 biologic therapies (range: 0-7). In addition, 6.1% (7/114) received concomitant systemic therapy alongside risankizumab. At baseline, the median PASI score was 11 (range: 0-50.2). The PASI score of 0 in two patients was attributed to one switching from infliximab due to comorbidity-related dosing concerns, and another with active psoriatic arthritis but minimal skin involvement (Table 1).

**Table 1.** Characteristics, demographics, and comorbidities of patients at baseline

Parameters	n (%)
Gender	
Male	72 (63.2)
Female	42 (36.8)
Age (y)	
Median	50
Minimum	18
Maximum	82
Phototype III	89 (78.1)
Disease duration (y), median	16
Minimum	1
Maximum	73
Special area involvement	70 (61.4)
Scalp	42 (36.8)
Nails	26 (22.8)
Palmoplantar	11 (9.6)
Genital	0
Psoriatic arthritis	31 (27.2)
PASI (median)	11
Concomitant systemic therapy	7 (6.1)
Methotrexate	5
Acitretin	2
Pre-treatment	
Bio-experiment	65 (57.0)
Bio-naïve	49 (43.0)
Arterial hypertension	46 (40.4)
Dyslipidemia	51 (44.7)
Major adverse cardiac events	2 (1.8)
Diabetes mellitus	15 (13.2)
Overweight	28 (24.6)
Obesity	29 (25.4)
Chronic kidney disease	4 (3.5)
Inflammatory bowel disease	2 (1.8)
Psychiatric	29 (25.4)
Neurological	0 (0)
Neoplasia (present or previous)	7 (6.1)
Human immunodeficiency virus	1 (0.9)
Hepatitis B virus	2 (1.8)
Hepatitis C virus	4 (3.5)
Treated latent tuberculosis	20 (18)

## Results

The median treatment duration was 76 weeks. At week 16 (n = 101) and ≥ 52 weeks (n = 97), PASI-75 was achieved by 89.1% and 92.8% of patients, PASI-90 by 71.3% and 86.6%, and PASI-100 by 61.4% and 79.4%, respectively. In difficult-to-treat areas, complete resolution was observed in 95.2% of patients with scalp involvement and 88.5% with nail psoriasis. In contrast, palmoplantar psoriasis showed lower response rates, with complete clearance achieved in 54.5% of cases. Among patients with psoriatic arthritis, 67.7% reached complete resolution. Incomplete responses were recorded in 4.8% of scalp cases, 7.7% of nail cases,

18.2% of palmoplantar cases, and 22.6% of psoriatic arthritis cases (Tables 2 and 3).

Concerning safety, three malignancies were diagnosed during treatment: one prostate adenocarcinoma, one in situ malignant melanoma, and one acute myeloid leukemia. Although no causal relationship with risankizumab was established, treatment was discontinued in the first and in the latter. No other AEs were reported during the observation period.

Overall, 12.3% (14/114) of patients discontinued treatment. The most common reason was primary efficacy failure (28.6%, 4/14) in two palmoplantar psoriasis and two psoriatic arthritis patients. Secondary efficacy failure accounted for another 28.6% (4/14), with one case each of nail, palmoplantar, plaque psoriasis, and psoriatic arthritis. One patient (7.1%) with psoriatic arthritis discontinued due to an incomplete response. Pregnancy led to discontinuation in three patients (21.4%). As mentioned above, two patients (14.2%) discontinued following cancer diagnoses.

## Discussion

RCT results may differ from real-world evidence, primarily due to the exclusion of medically complex patients. Our cohort represented a more heterogeneous population, with a higher prevalence of comorbidities and a greater proportion of bio-experienced patients (57% in our cohort vs. 34% in the UltIMMa-1 trial)<sup>5</sup>.

Nevertheless, at week 16, PASI-90 was achieved by 71.3% of patients, outperforming real-world studies (54.4%<sup>8</sup>) and closely aligning with RCT results (73.8%<sup>6</sup>). By ≥ 52 weeks, PASI-90 increased to 86.6%, matching or surpassing both real-world (81.48-90.7%<sup>9</sup>) and RCT data (86.6%<sup>6</sup>). Notably, 61.4% of patients achieved PASI-100 at week 16, exceeding reported outcomes from real-world data (35.4%<sup>8</sup>) and RCTs (44.0%<sup>6</sup>). This response improved to 79.4% at ≥ 52 weeks, again surpassing previous real-world (46.09-65.7%<sup>8</sup>) and RCT findings (65.9%<sup>6</sup>).

Results for scalp and nail psoriasis were in line with existing data, while outcomes for palmoplantar psoriasis were less favorable<sup>10,11</sup>. Complete resolution of scalp psoriasis was achieved in 95.2% of patients, compared to 85%<sup>10</sup> in RCTs and 98%<sup>11</sup> in other real-world studies. Nail psoriasis resolved completely in 88.5%, exceeding RCT (71%)<sup>10</sup> and real-world (82%)<sup>11</sup> rates. Palmoplantar psoriasis, however, showed lower response rates, with complete resolution in only 54.5% of patients, considerably below the 93% reported in both RCTs and real-world studies<sup>10,11</sup>.

**Table 2.** Treatment response to risankizumab in difficult-to-treat areas

Response	Scalp, n (%)	Palmoplantar, n (%)	Nails, n (%)	Psoriatic arthritis, n (%)
Complete	40 (95.2)	6 (54.5)	23 (88.5)	21 (67.7)
Incomplete	2 (4.8)	2 (18.2)	2 (7.7)	7 (22.6)
Primary failure	0 (0)	2 (18.2)	0 (0)	2 (6.5)
Secondary failure	0 (0)	1 (9.1)	1 (3.8)	1 (3.2)

**Table 3.** Clinical effectiveness and safety outcomes of risankizumab

Parameters	n (%)
Efficacy	
Week-16, (n = 101)	
PASI-75	90 (89.1)
PASI-90	72 (71.3)
PASI-100	62 (61.4)
Week ≥ 52, (n = 97)	
PASI-75	90 (92.8)
PASI-90	72 (86.6)
PASI-100	77 (79.4)
Complete response in difficult-to-treat areas	
Scalp	40 (95.2)
Palmoplantar	6 (54.5)
Nails	23 (88.5)
Psoriatic arthritis	21 (67.7)
Safety	
One or more adverse events	3 (2.63)
Discontinuation	14 (12.3)
Discontinued due to primary efficacy failure	4/14 (28.6)
Palmoplantar psoriasis	2/4
Psoriatic arthritis	2/4
Discontinued due to secondary efficacy failure	4/14 (28.6)
Nail psoriasis	1/4
Palmoplantar psoriasis	1/4
Plaque psoriasis	1/4
Psoriatic arthritis	1/4
Discontinued due to incomplete response psoriatic arthritis	1/14 (7.1)
Discontinued due to pregnancy	3/14 (21.4)
Discontinued due to adverse events	2/14 (14.2)
Prostate adenocarcinoma diagnosis	1/2
Acute myeloid leukemia diagnosis	1/2

This may reflect the distinct pathophysiology of palmoplantar psoriasis, where mechanical stress and friction can limit therapeutic success. As observed in previous studies, palmoplantar psoriasis remains challenging with variable response rates across different biologics<sup>12</sup>.

Safety findings in our cohort were more favorable compared to published data. While AEs are reported in up to 71.3% of RCT participants<sup>6</sup>, real-world studies suggest a lower incidence (~7%<sup>8</sup>). In our cohort, three cases of malignancy were observed; however, no causal relationship with risankizumab was established.

The strengths of our study include a relatively large single-center cohort (n = 114), the inclusion of diverse psoriasis subtypes, and an extended follow-up (median 76 weeks), enabling robust assessment of both short- and long-term effectiveness and safety. Nonetheless, the study has some limitations. The absence of a control group limits direct comparisons, and variability in clinical assessments performed by different physicians may introduce bias. Furthermore, the frequency of AEs may have been underestimated, as mild or transient side effects are often not reported in routine clinical practice.

## Conclusion

To conclude, our real-world data confirm the efficacy and safety of risankizumab in plaque, scalp, and nail psoriasis, with outcomes comparable to or exceeding those observed in RCTs and other real-world studies. Risankizumab has demonstrated strong therapeutic potency, providing rapid and significant improvement early in treatment. Moreover, its efficacy persists over time, with responses not only maintained but often improving with continued therapy. Nevertheless, larger real-world cohort studies with comparators are needed.

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None.

## Conflicts of interest

A. Ferreira, C. Valente, I. Aparício-Martins have no conflicts of interest to declare; M.J. Paiva-Lopes has received honoraria from AbbVie, Ammirall, Boehringer

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## Ethical considerations

**Protection of humans and animals.** The authors declare that the procedures followed complied with the ethical standards of the responsible human experimentation committee and adhered to the World Medical Association and the Declaration of Helsinki. The procedures were approved by the institutional Ethics Committee.

**Confidentiality, informed consent, and ethical approval.** The authors have obtained approval from the Ethics Committee for the analysis of routinely obtained and anonymized clinical data, so informed consent was not necessary. Relevant guidelines were followed.

**Declaration on the use of artificial intelligence.** The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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