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REVIEW

Effectiveness of risankizumab in the treatment of palmoplantar psoriasis: a 52-week Italian real-life experience

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Abstract

Background: Data on the treatment of palmoplantar psoriasis (PP) are scarce, representing a therapeutic challenge. This study aims to assess the efficacy and safety of risankizumab in a population of patients with psoriasis with a palmoplantar involvement, over a 52-week treatment period.

Methods: We performed a retrospective analysis in a cohort of patients with PP, with or without involvement of other skin sites. Palmoplantar Psoriasis Area and Severity Index (ppPASI) was assessed at baseline and after 4, 16, 28 and 52 weeks, to evaluate the PP severity.

Results: Sixteen patients were enrolled. The rates of ppPASI90 responses constantly increased during the period of observation and were 18.7%, 62.2%, 75.0% and 81.2% at weeks 4, 16, 28 and 52, respectively. Only two patients suspended treatment because of ineffectiveness at week 16.

Conclusion: Our data from a series of 16 patients reveal that risankizumab could represent an effective and safe therapeutic choice in patients with PP.

Keywords: efficacy, IL-23, psoriasis, real-life, risankizumab, safety.

Citation

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Introduction

Palmoplantar psoriasis (PP) consists of erythematous, hyperkeratotic plaques that may be associated with painful and disabling fissures.[1] This presentation may be the unique localization of psoriasis, accounting for 3–4% of all cases[2] or be associated to other site involvement. Currently, several biological treatments, in addition to first-line therapies like retinoids, methotrexate or small molecules, have been suggested as effective options. However, there are limited data on the treatment of this area since only few clinical trials have been designed to evaluate it specifically.[3,4] Moreover, PP is frequently resistant to therapies, making it difficult to treat.[1]

Risankizumab is a humanized immunoglobulin (Ig) G1 monoclonal antibody directed against the p19 subunit of IL-23, and has been approved by the European Medicines Agency since 2019 for the treatment of moderate-to-severe plaque psoriasis in adult patients who have indication for systemic therapy or phototherapy.[5] Several authors have already reported their experiences in real-world clinical practice, confirming its short-term and long-term effectiveness in plaque psoriasis.[6,7] Some data have also been reported about

its effectiveness in difficult-to-treat areas, such as nails and scalp[8,9] but few data are available regarding its use for PP.[9–13]

The objective of this multicentre, retrospective study was to evaluate the efficacy and safety of risankizumab in a population of patients with psoriasis with palmoplantar involvement over a 52-week treatment period.

Patients and methods

We performed a retrospective analysis in a cohort of adult patients with PP, with or without involvement of other skin sites, who started treatment with risankizumab between December 2019 and February 2021. The study population was composed of patients attending the dermatological clinics of the four participating centres (Fondazione Policlinico Universitario A. Gemelli IRCCS; Università Campus Biomedico; Istituto Dermopatico dell'Immacolata – IDI; Policlinico Tor Vergata) in Lazio, Italy. Patients with pustular PP were excluded from the study, as were patients who concurrently received any other antipsoriatic systemic therapy or who received risankizumab at unscheduled dosages. For each patient, demographic and clinical data and previous therapeutic history were collected at the time of initiation of biological therapy. The severity of PP was estimated by the Palmoplantar Psoriasis Area and Severity Index[14] (ppPASI) – measured at baseline and after 4, 16, 28 and 52 weeks. Standard PASI score was also recorded at the same time points in patients with other site involvement. Data were summarized using descriptive statistics (mean ± standard deviation (SD) for continuous variables and number and percentage for categorical variables). Data about potential safety issues and adverse events were also collected.

The entire study was conducted according to the principles of the Helsinki Declaration. Institutional review board approval was not required for this study because the procedures did not deviate from routine clinical practice. Informed consent was obtained.

Table 1. Clinical and demographic characteristics of the study population.

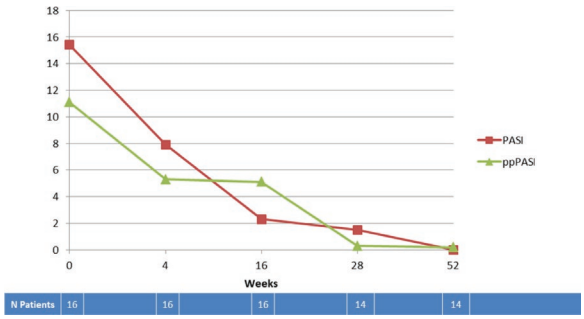
Characteristics (total *n*=16)		*n* (%) (unless otherwise stated)
Sex	Male	10 (62.5)
	Female	6 (37.5)
Age, mean (SD)		47.9 (13.7)
BMI, mean (SD)		28.9 (4.6)
Comorbidities	Psoriatic arthritis	2 (12.5)
	Hypertension	4 (25.0)
	Diabetes	3 (18.7)
	Dyslipidemia	4 (25.0)
	Ulcerative colitis	1 (6.2)
	Thyroiditis	2 (12.5)
Age of onset, mean (SD)		28.8 (18.1)
Other skin site involvement	No	4 (25.0)
	Yes	12 (75.0)
Previous treatment	Phototherapy	2 (12.5)
	CyA	8 (50.0)
	Methotrexate	6 (37.5)
	Acitretin	5 (31.2)
	Etanercept	2 (12.5)
	Adalimumab	5 (31.2)
	Ustekinumab	1 (6.2)
	Secukinumab	4 (25.0)
	Ixekizumab	1 (6.2)
	Guselkumab	1 (6.2)
Last biological treatment	Naive	7 (43.7)
	Anti-TNFα	3 (18.7)
	Anti-IL-17	4 (25.0)
	Anti-IL-23 or anti-IL-12/23	2 (12.5)
Treatment suspension	No	14 (87.5)
	Yes	2 (12.5)
ppPASI at baseline, mean (SD)		11.1 (5.5)
PASI at baseline, mean (SD)		15.4 (9.9)

CyA, cyclosporin A; BMI, body mass index; PASI, Psoriasis Area and Severity Index, pp, palmoplantar.

Results

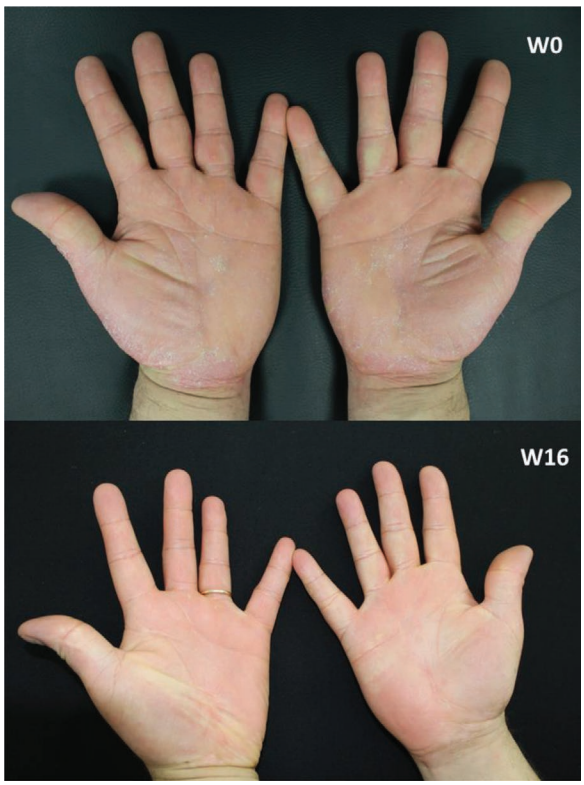
Sixteen patients were enrolled and their demographic and clinical characteristics at the beginning of treatment are summarized in Table 1. PASI and ppPASI decreased rapidly after the first 4 weeks of treatment and continued to decrease with a similar trend (Figures 1 and 2). The rates of ppPASI90 responses constantly increased during the period of observation and were 18.7% (3/16), 62.2% (10/16), 75.0% (12/16) and 81.2% (13/16) at weeks 4, 16, 28 and 52, respectively. Moreover, the rates of ppPASI100 responses were 12.5% (2/16), 56.2% (9/16), 68.7% (11/16) and 75.0% (12/16) at the same time

Figure 1. Mean PASI and ppPASI variations during the observation period (as observed analysis).



pp, palmoplantar; PASI, Psoriasis Area and Severity Index.

Figure 2. Clinical pictures of an enrolled patient.



W, week.

points. Only 2 (12.5%) patients suspended the treatment because of ineffectiveness at week 16: one patient was bio-naive and with other skin site involvement, and one patient had previously received secukinumab and had only PP involvement. No mild or serious safety issues occurred during the observation period, and no discontinuations related to adverse events were reported.

Discussion

This observational study showed that risankizumab is an effective therapeutic option for psoriasis in difficult-to-treat sites such as palms and soles. In fact, whilst previous treatments had proved largely ineffective, risankizumab induced a rapid improvement in PP as well as in concomitant plaques psoriasis in these patients. This rapidity of action is consistent with some previously published cases[10,11] that reported an almost complete clearance of PP even after the first two drug injections. Similar data were also reported by Megna et al., who compared the efficacy of guselkumab, risankizumab and tildrakizumab in a 28-week retrospective study.[12] They found all three drugs displayed a high efficacy in palmoplantar involvement, with a body surface area reduction for risankizumab of 41.9%, 94.8% and 91.7%, respectively, at weeks 4, 16 and 28.

In our opinion, these real-life experiences are very supportive because no clinical trials ad hoc have been designed to evaluate the efficacy of risankizumab in PP and, to date, only a sub-analysis of the LIMMitless study is available.[15] This sub-analysis reported a mean ppPASI improvement from baseline of >97% at week 256, with >81% of 164 patients with psoriasis with palmoplantar involvement achieving ppPASI = 0.

Although our small sample size did not permit the performance of statistical analyses nor evaluation of the impact of the clinical and demographic factors on drug response, we consider worthy of note that, in our population, more than half of patients were bio-experienced and that the drug was effective in patients with and without other skin site involvement. However, this study has several limitations in addition to the small sample size, including the retrospective design and absence of a control group. Moreover, although patients receiving any other antipsoriatic systemic therapy were not enrolled in this study, we cannot rule out the possibility that they may have applied some topical therapies. Finally, data about smoking habits were not available. Despite these limitations, we consider our experience noteworthy because it is amongst the first reported experiences with risankizumab in this subpopulation of patients with psoriasis and because of the relatively long follow-up period.

Conclusion

Our data from a series of 16 patients demonstrate that risankizumab could represent an effective and safe therapeutic option in patients affected by PP as previously reported only in few isolated cases.[10–13] However, longer longitudinal prospective studies with larger cohorts of patients are needed to confirm these results.

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