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LETTER TO THE EDITOR

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Effectiveness of risankizumab in plaque psoriasis with involvement of difficult-to-treat areas: a real-world experience from two referral centers

Introduction

Plaque psoriasis most commonly occurs on the elbows, knees, and lumbosacral region, but it can affect any body surface (1). Plaque psoriasis can also affect areas such as the scalp/face (43–65%), nails (23–60%), palms/soles (12–26%), and genitalia (14–43%), which have been described as difficult-to-treat areas (2–5). Treatment of these patients can be challenging due to inadequate response to topical corticosteroids and vitamin D derivatives (5). Cyclosporine and methotrexate are options, however, long-term treatment with cyclosporin causes renal dysfunction, hypertension, and blood count abnormalities, and methotrexate is associated with hepatic and hematological toxicities (6).

Biologics offer safer alternatives, but there are limited data regarding their efficacy in patients with difficult-to-treat sites. Moreover, patients with limited disease extent are usually excluded from phase III clinical trials, despite the severe involvement of these areas (4). Risankizumab is a highly effective and very safe inhibitor of interleukin (IL)-23 evaluated in clinical trials and real-world experiences (7,8). However, there is still a paucity of data regarding the use of this drug in psoriatic patients with moderate-to-severe involvement of the scalp, nails, palms/soles, and genitalia. The purpose of this study was to assess real-world risankizumab efficacy and safety in patients with psoriasis in these areas.

Methods

We conducted a 52-week retrospective study from two Dermatology Units to evaluate the effectiveness of risankizumab in patients with moderate-to-severe involvement of at least one difficult-to-treat area (defined by a site-specific Physician's Global Assessment ≥ 3). Risankizumab was administered according to the Summary of Product Characteristics (9). Scalp-specific Physician's Global Assessment (sc-PGA), palmoplantar PGA (ppPGA), static Physician's Global Assessment of Genitalia (sPGA-G), fingernail PGA (f-PGA), and Psoriasis Area and Severity Index (PASI) were recorded at each dermatological examination. Any adverse events (AEs) during the visits were also evaluated. The primary endpoints were the proportion of patients achieving a site-specific PGA of 0/1 (clear or almost clear) at weeks 16, 28, and 52.

Continuous data were reported as mean and standard deviation (SD), while categorical variables were presented as absolute numbers and percentages. The within-group comparison of mean-PGA (between baseline with weeks 16, 28, and 52) was performed by the Student's *t*-test.

Results

We included 202 patients treated with risankizumab for at least 52 weeks (Table 1). One hundred and thirty-three were males (65.8%) with a mean age of 50.43 (SD 15.95). Our patients were affected by psoriasis for a mean of 17.27 years (SD 14.32). The mean body mass index (BMI) was 27.37 (SD 5.30), while 72 patients had at least one cardiometabolic comorbidity (arterial hypertension, obesity, type II diabetes mellitus, hypercholesterolemia, and cardiovascular diseases). Forty-six patients had previously received at least one biological drug (22.8%). Regarding the 165 patients with scalp involvement, sc-PGA of 0/1 was achieved in 86.7% ($n = 143$), 97.6% ($n = 161$), and 97.6% ($n = 161$) of them at weeks 16, 28, and 52, respectively (Figure 1(a)). Twenty-one patients were affected by palmoplantar psoriasis. After 16 weeks, 52% ($n = 11$) of them achieved a ppPGA of 0/1, with continuous improvement at weeks 28 (76%, $n = 16$) and 52 (95%, $n = 20$) (Figure 1(b)). Among the 72 patients with genital psoriasis, sPGA-G of 0/1 was observed in 85% ($n = 61$) at week 16, 93% ($n = 67$) at week 28, and 100% ($n = 72$) after one year (Figure 1(c)). Finally, 50 patients presented with nail psoriasis. A f-PGA of clear or almost clear was reached by 38% ($n = 19$) at week 16, 68% ($n = 34$) at week 28 and 82% ($n = 41$) at week 52 (Figure 1(d)). Mean PGA improved in each difficult-to-treat area. At baseline, the mean sc-PGA was 3.33 and decreased to 0.51 at week 15, 0.23 at week 28 and 0.16 after one year of treatment (Figure 2(a)). Mean pp-PGA decreased from a mean of 3.19 at baseline to 1.38 at week 16, 0.81 at week 28, and 0.43 at week 52 (Figure 2(b)). Mean sPGA-G decreased from a mean of 3.32

Table 1. Demographic characteristics and disease severity scores at baseline of our population.

Number of patients, N	202
Males, N (%)	133 (65.8)
Age, mean ± SD	50.43 ± 15.95
BMI, mean ± SD	27.37 ± 5.30
Disease Duration, mean ± SD	17.27 ± 14.32
PsA, N (%)	20 (9.9)
≥1 Difficult-to-treat areas, N (%)	87 (43.1)
Cardiometabolic comorbidities	72 (35.6)
Bio-Naïve, N (%)	156 (77.2)
PASI baseline, mean ± SD	14.79 ± 8.55
sc-PGA ≥4, N (%)	53 (32.1)
pp-PGA ≥4, N (%)	4 (19.1)
sPGA-*G* ≥ 4, N (%)	23 (31.9)
f-PGA ≥4, N (%)	13 (26)

Abbreviation: BMI: Body Mass Index; PsA: Psoriatic Arthritis; PASI: Psoriasis Area and Severity Index; sc-PGA: scalp-specific Physician's Global Assessment; pp-PGA: palmoplantar PGA sPGA-G: static Physician's Global Assessment of Genitalia; f-PGA: fingernail PGA.

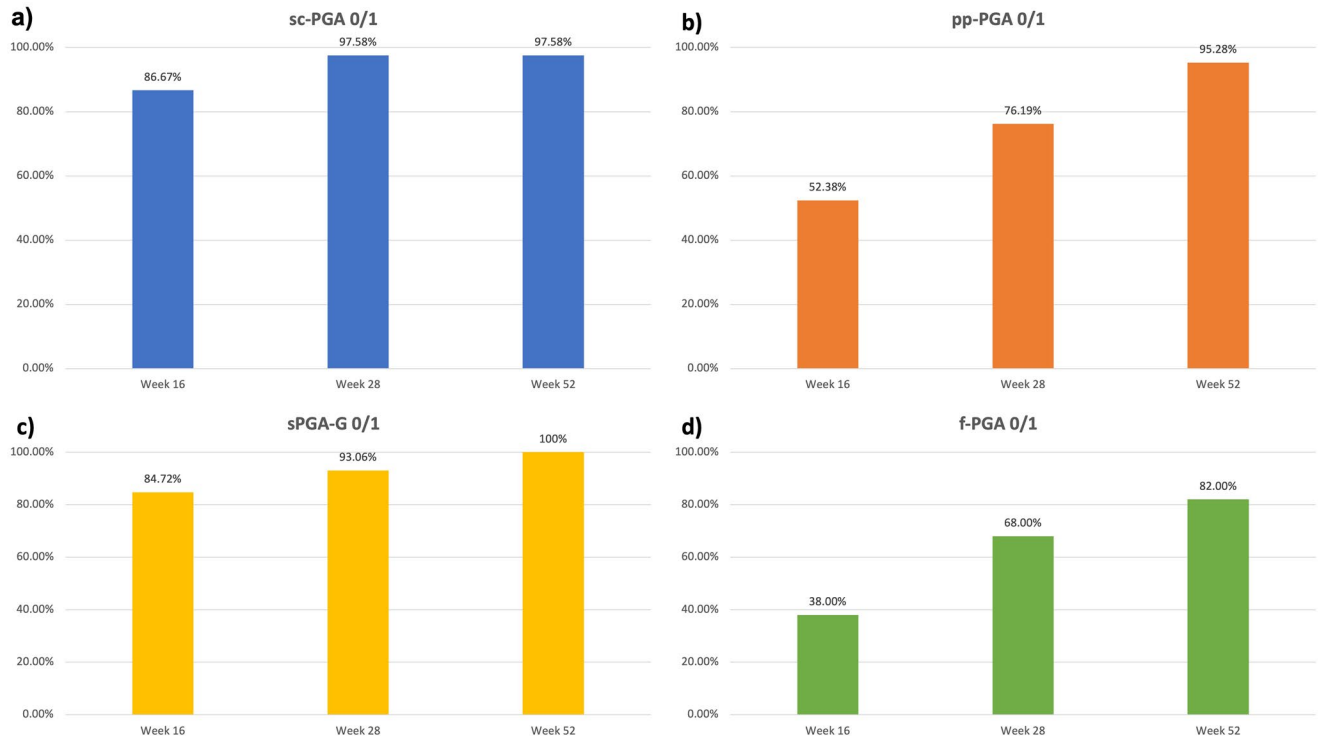

Figure 1. Percentage of patients achieving sc-PGA (1a), pp-PGA (1b), sPGA-G (1c) and f-PGA (1d) of 0 or 1 (clear and almost clear) at weeks 16, 28 and 52.
Abbreviation: sc-PGA: scalp-specific Physician's Global Assessment; pp-PGA: palmoplantar PGA sPGA-G: static Physician's Global Assessment of Genitalia; f-PGA: fingernail PGA.

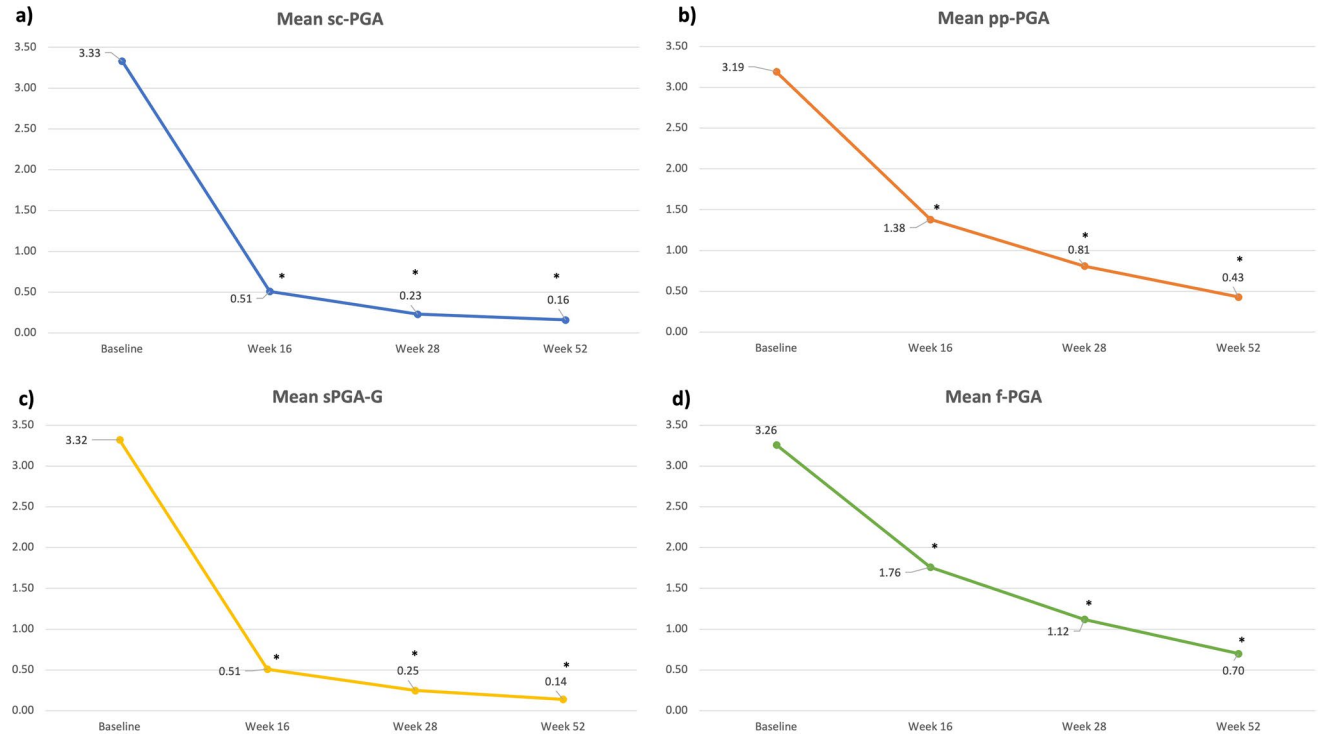

Figure 2. Mean site-specific PGA of our population at baseline, week 16, week 28 and week 52.
Abbreviation: sc-PGA: scalp-specific Physician's Global Assessment; pp-PGA: palmoplantar PGA sPGA-G: static Physician's Global Assessment of Genitalia; f-PGA: fingernail PGA; * p-value < 0.001.

at baseline to 0.51, 0.25, and 0.14 at the same time points (Figure 2(c)). Mean f-PGA was 3.26 at baseline and decreased to 1.76 at week 16, 1.12 at week 28, and 0.70 after 52 weeks of treatment (Figure 2(d)). No significant safety findings were reported during the study, as no patient had to discontinue the drug because of treatment-emergent AEs or serious AEs.

Conclusions

Despite a large number of real-world studies and clinical trials on the efficacy of biologics in plaque psoriasis, few studies have focused on difficult-to-treat areas (10,11). Regarding IL-17 inhibitors, there have been clinical trials focused on difficult-to-treat sites: in particular, ixekizumab is effective for genital psoriasis (12) and secukinumab for psoriasis involving the palms or soles (13). Data from clinical trials regarding the role of anti-IL-23 drugs in treating these areas are currently limited. However, IL-23 inhibitors have comparable effectiveness in real-world experiences in patients with and without the involvement of difficult-to-treat areas (14–17). In our study, risankizumab was rapidly effective, particularly in patients with scalp and genital psoriasis, which improved patient well-being.

Acknowledgements

None.

Ethical approval

Institutional review board approval was exempted as the study protocol did not deviate from standard clinical practice. The patient received risankizumab as in good clinical practice, in accordance with European guidelines. The patient and her parents had provided written consent for retrospective study of data collected during routine clinical practice (demographics, clinical scores) and for the publication of clinical pictures. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Data collection and handling complied with applicable laws, regulations, and guidance regarding patient protection, including patient privacy.

Disclosure statement

L. Gargiulo has been a consultant for Almirall. M. Valenti has been a consultant and/or speaker for Sanofi, Leo Pharma, Eli Lilly, Novartis, Janssen, AbbVie and Boehringer Ingelheim. A. Costanzo has served as an advisory board member, consultant and has received fees and speaker's honoraria or has participated in clinical trials for Abbvie, Almirall, Biogen, LEO Pharma, Lilly, Janssen, Novartis, Pfizer, Sanofi Genzyme, and UCB-Pharma. A. Narcisi has served on advisory boards, received honoraria for lectures and research grants from Almirall, Abbvie, Leo Pharma, Celgene, Eli Lilly, Janssen, Novartis, Sanofi-Genzyme, Amgen and Boehringer Ingelheim. The other authors have nothing to disclose.

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Data availability statement

Data are available on request from the authors.

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