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SHORT REPORT

Ustekinumab is effective and safe in the long-term treatment of erythrodermic psoriasis: Multicenter study in daily practice

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Abstract

Background: The treatment of erythrodermic psoriasis (EP) is challenging. Biological therapies have shown promising results in the long-term management of this clinical variant, but most of the current available evidence is based on single case reports and short case series.

Objectives: To determine the effectiveness and safety of ustekinumab (UST) in the treatment of EP under daily practice conditions.

Methods: We conducted a retrospective, observational, nationwide, multicenter cohort study of patients diagnosed with EP treated with UST under daily practice conditions with up to 3 years of follow-up. Outcomes, such as the psoriasis area and severity index (PASI) and safety, were assessed at months 1, 4, 7, 13, 19, 25, 31 and 37 during treatment. "As observed" and "intention-to-treat last observation carried forward (ITT-LOCF)" analyses were performed.

Results: Twenty-eight patients were enroled in the study. Baseline mean PASI was 43.1. A sharp decrease in mean PASI was observed during the first 7 months, reaching a plateau that was maintained until the end of the 37-month follow-up. At 7 months, 61% and 43% of the patients achieved PASI ≤ 2 and PASI 0, respectively. At 25 months, 48 (39%) ("as observed"/ITT-LOCF) of the patients achieved complete clearance. At 31 months, PASI 75, PASI 90 and PASI 100 were achieved in 95, 80 and 45 (79%, 64% and 39%) ("as observed"/ITT-LOCF) of the patients, respectively. Eleven patients required treatment intensification by reducing the interval between doses. Treatment minimisation was performed in four patients. During the follow-up, nine patients (32%) received systemic combination therapy at some point. Eight patients discontinued treatment

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mainly due to lack of effectiveness. UST presented a good safety profile. With a follow-up of 69.25 patient/years, only three patients exhibited serious nondrug-related adverse events.

Conclusions: Ustekinumab can be a fast, effective and safe alternative for the long-term treatment of erythrodermic psoriasis.

KEYWORDS
biologic therapy, daily practice, erythrodermic psoriasis, ustekinumab

INTRODUCTION

Erythrodermic psoriasis (EP) is a rare and severe psoriasis subtype. The treatment of this clinical form of psoriasis is challenging due to its low incidence and the exclusion of EP patients from pivotal trials. Therefore, the evidence supporting the efficacy of systemic drugs for treating EP is mainly based on case reports and small case series.[1–5]

Ustekinumab (UST) is a fully human monoclonal antibody targeting the p40 subunit shared by interleukin 12 and 23, approved for the treatment of moderate-to-severe plaque psoriasis.[4] There is a lack of randomised, double-blind, controlled trials and head-to-head comparisons for the treatment of EP with UST.[1] Moreover, focusing on daily practice, only short-term retrospective studies and case reports have shown UST effectiveness in patients with this clinical variant.[6–14]

The objective of this study was to determine the effectiveness and safety of UST for the treatment of patients with EP under daily practice conditions.

METHODS

We designed a retrospective, observational, nationwide, multicenter cohort study of patients with EP treated with UST in daily practice between January 2009 and October 2020. All members of the Psoriasis Working Group of the Spanish Academy of Dermatology and Venereology were invited to participate in the study. Finally, dermatologists from 10 hospitals all around Spain took part in this nonsponsored study.

The following inclusion criteria were applied, adults diagnosed with EP (involvement of ≥90% of body surface area) treated with UST in a daily practice setting, with a follow-up of at least 7 months (maximum 37 months). Patients were scheduled to receive initially UST 45 mg (for weight ≤ 100 kg) or 90 mg (for weight > 100 kg) subcutaneous injections, according to the label and guidelines for moderate-to-severe plaque psoriasis treatment, at Weeks 0 and 4, and thereafter every 12 weeks. Psoriasis area and severity index (PASI) and body surface area (BSA) were assessed at baseline and at Months 1, 4, 7, 13, 19, 25, 31 and 37 during treatment. Absolute PASI (≤5, ≤2 and 0), 75%, 90% and 100% reduction in PASI from baseline (PASI 75, PASI 90 and PASI 100 responses), as well as the safety profile were registered in every monitoring visit. Disease severity was assessed through absolute PASI at base line. UST response was evaluated through change in PASI and absolute PASI, using both, "as observed" and "intention-to-treat last observation carried forward (ITT-LOCF)" analyses.

RESULTS

Twenty-eight Caucasian patients were included in the study. Baseline characteristics are summarised in Table 1. The significant proportion of male patients (78%) is noteworthy. Three (11%) and 12 (43%) patients were naïve to conventional and biologic systemic therapy, respectively.

Twenty patients (53%) completed a follow-up period of 37 months. Eight patients (28%) discontinued treatment during the follow-up: 5 (17%) due to inefficacy (after 7, 13 and 19 months), 2 (7%) due to loss to follow-up (after 7 and 19 months) and one (3%) due to sustained clearance (after 25 months). Median time to UST discontinuation was 32 months (interquartile range: 7–37 months). Discontinuations are summarised in a flow chart (Figure 1).

The response to UST was first observed at Week 4, when PASI decreased to a mean value of 16.6 (range 0–50.1) with a 61% improvement from baseline. After 28 weeks, mean PASI was 5.1 (range 0–36) with an 88% improvement from baseline PASI. Twenty patients were still receiving UST at the end of the follow-up period (37 months) with a median PASI of 1.9 (mean 3.1, range: 0–14.7. Data as observed).

Both absolute and relative PASI evolution throughout the study are shown in Figures 2 and 3, respectively. Absolute PASI ≤ 2 was achieved by almost half of the

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TABLE 1 Baseline demographic and clinical characteristics of the patients.

Variable	Category	*N* (%) or mean (SD)
Sex, *n* (%)	Male	22 (79%)
	Female	6 (21%)
Age, years, mean (SD)		52.6 (16.8)
Disease duration (years) mean (SD)		22.75 (13.6)
	<10 years	6 (21%)
	10–20 years	4 (14%)
	20–30 years	6 (21%)
	>30 years	6 (21%)
Weight, kg, mean (SD)		83.6 (21.2)
Height, cm, mean (SD)		172.9 (7.7)
BMI, kg/m^2, mean (SD)		27.8 (5.7)
	Normal weight (<25)	8 (29%)
	Overweight (25–29)	13 (46%)
	Obesity (≥30)	6 (21%)
Comorbidities, *n* (%)		
	Psoriatic arthritis	4 (14%)
	Dyslipidemia	7 (25%)
	Diabetes mellitus	4 (14%)
	Hypertension	9 (32%)
Previous conventional systemic psoriasis treatment, *n* (%)	MTX	25 (89%)
		14 (50%)
	CyA	17 (61%)
	ACI	16 (57%)
	PUVA or nbUVB	22 (79%)
Naive to conventional systemic psoriasis treatment, *n* (%)		3 (11%)
Previous biologic psoriasis treatment, *n* (%)	1 biologic	16 (57%)
		9 (56%)
	2 biologics	3 (19%)
	3 biologics	2 (13%)
	4 biologics	2 (13%)
Type of previous biologic psoriasis treatment, *n* (%)	Infliximab	11 (39%)
	Adalimumab	7 (25%)
	Etanercept	8 (29%)
	Efalizumab	3 (11%)
Naive to biologic previous treatment, *n* (%)		12 (43%)
Measure of disease activity, mean (SD)	Baseline PASI	43.1 (12.3)
	BSA	90.2 (0.9)

Abbreviations: ACI, acitretin; BMI, body mass index; BSA, body surface area; CyA, cyclosporine; MTX, methotrexate; nbUVB, narrow-band ultraviolet B therapy; PASI, psoriasis area and severity index; PUVA, psoralen and ultraviolet A therapy; SD, standard deviation.

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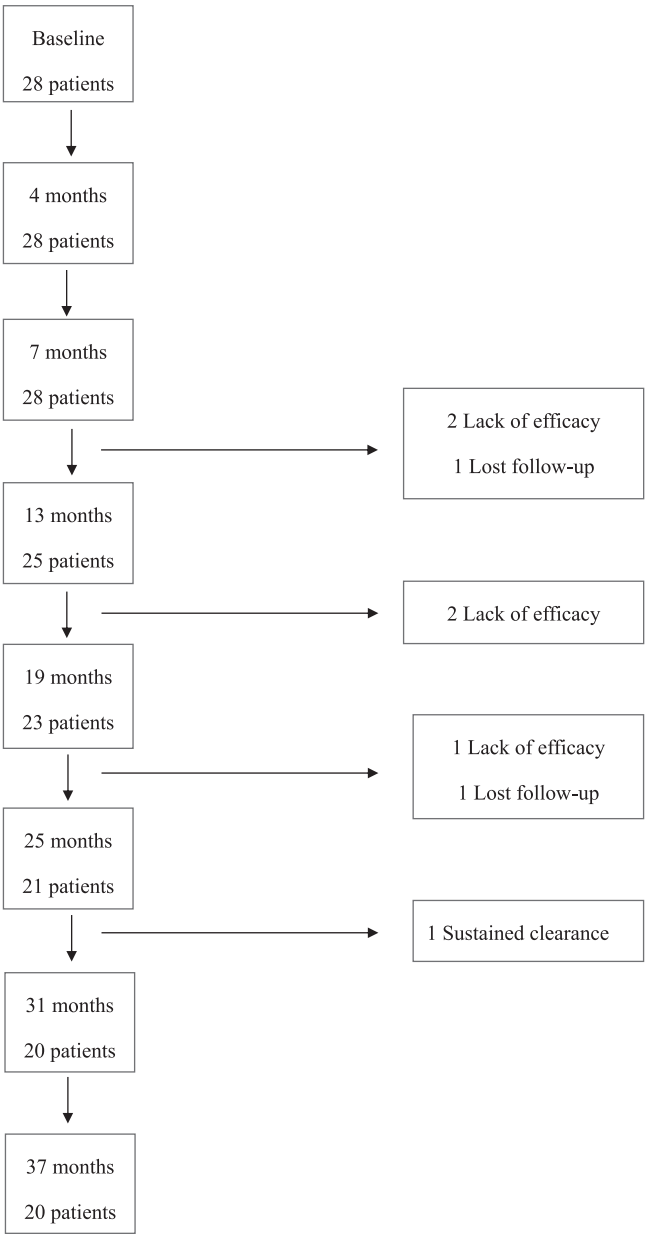

FIGURE 1 Flow chart and definitive discontinuations.

patients (13, 46%) after only 4 months of treatment with UST. After 7 months, 17 (61%) and 12 (43%) patients achieved PASI ≤ 2 and PASI 0 (complete clearance), respectively. At 25 months, 48/39% ("as observed"/ITT – LOCF analysis) of the patients achieved a complete clearance. Sustained effectiveness was obtained in most of the patients within 37 months. A PASI 75 response was achieved by 84%, 91% and 95% of patients at 13, 19 and 25 months of treatment, respectively, as assessed by "as observed" analysis. At 31 months, PASI 75, PASI 90 and PASI 100 was achieved in 95/79%, 80/64% and 45/39% respectively, assessed by "as observed"/ITT-LOCF analysis.

The mean body surface area also showed a rapid improvement from 90.2% to 39.5% after 4 weeks and administration of only one UST dose. Eleven patients (39%) achieved BSA 0 after a second UST dose. BSA was assessed throughout the study, showing a decrease in parallel with the improvement in PASI.

We could not find any correlation between clinical factors (body mass index, previous treatment, duration of EP) and UST effectiveness.

The initial label-based administration regimen of UST was modified in 15 patients (39%) throughout the study. Eleven patients (29%) required treatment intensification by reducing the interval between doses, maintaining this pattern throughout the study. In three patients (8%), treatment intensification was initiated in the 4th month of therapy. At Month 25, eight patients (21%) were under treatment intensification. Treatment optimisation was performed in four patients (11%) by lengthening the interval between UST administrations (the first patient started at Month 13 and the remaining 3 at Month 25).

At baseline there were two patients (5%) in combination therapy with cyclosporine (in both, cyclosporine was discontinued 4 weeks after starting UST), one with methotrexate (3%) and another one (3%) with acitretin. During the follow-up, nine patients (32%) received systemic combination therapy (four methotrexate, two cyclosporine, one methotrexate and cyclosporine, and two acitretin) at some point.

Since adverse event reporting was not standardised, only serious adverse events (SAE) were considered. With a follow-up of 69.25 patient/years, only three patients presented SAE: cholelithiasis with cholecystectomy, angina pectoris (at Month 25), and aortic aneurysm (at Month 37). These SAE were not considered to be drug-related by the researchers and none of the patients required treatment discontinuation. There were no cases of injection site reactions, death, neoplasms, serious infections (including tuberculosis), depression, or reactivation of intestinal inflammatory diseases.

DISCUSSION

We have only found three series of patients with EP treated with UST in real-world including three or more patients.[10,13,14] Stinco et al. described three patients who achieved PASI50 at Week 4 and complete clearance at Weeks 19, 21 and 28.[13] Wang et al. reported eight patients, with no response observed until 8 weeks of treatment and lack of total clearance after 28 weeks of follow-up.[14] Finally, Pescitelli et al described the largest series in the literature, a multicenter retrospective study

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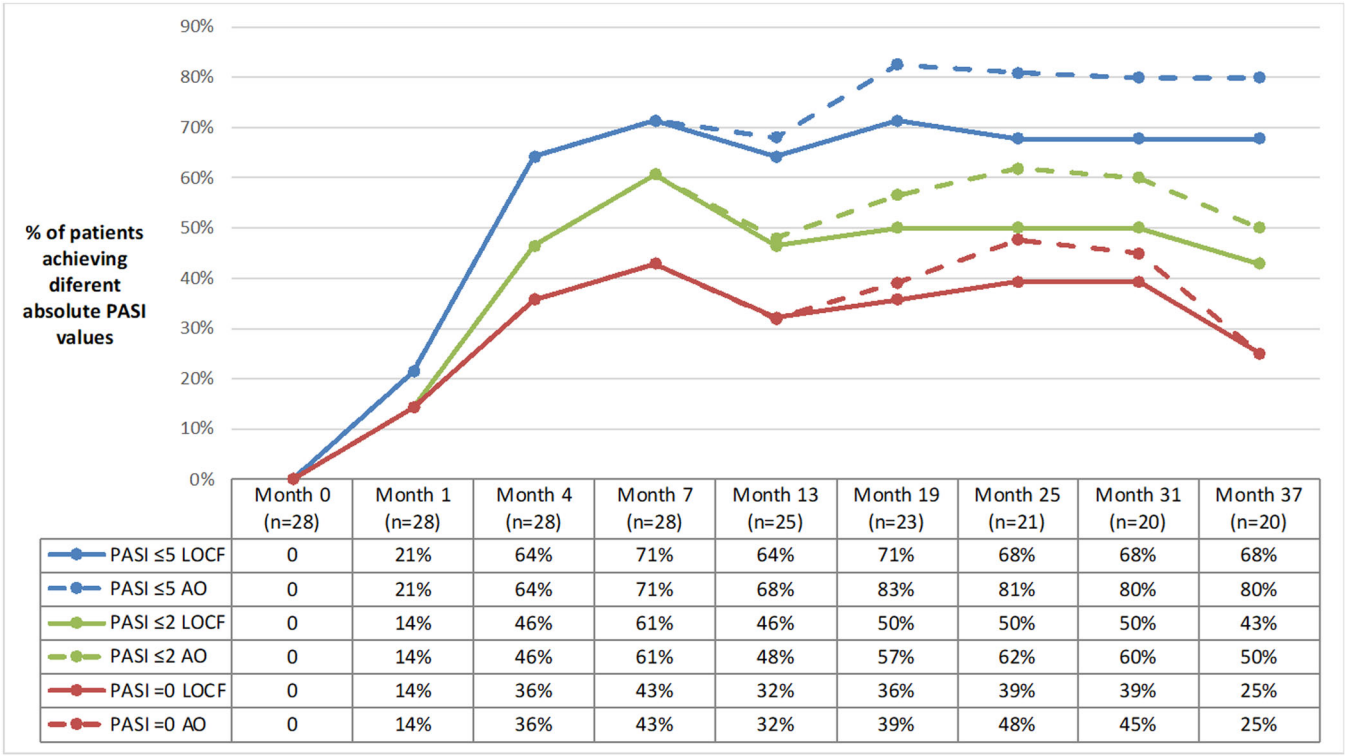
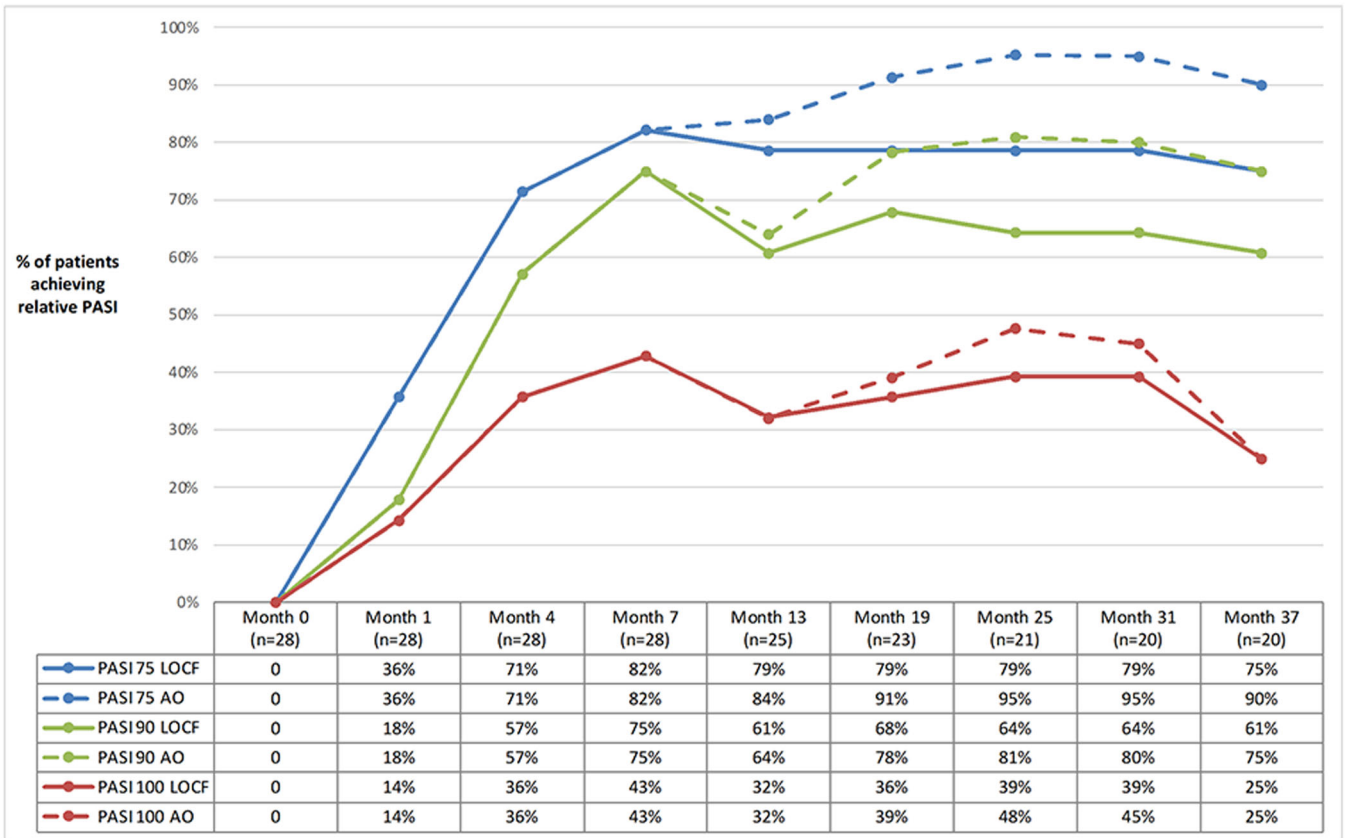


	Month 0 (n=28)	Month 1 (n=28)	Month 4 (n=28)	Month 7 (n=28)	Month 13 (n=25)	Month 19 (n=23)	Month 25 (n=21)	Month 31 (n=20)	Month 37 (n=20)
PASI ≤5 LOCF	0	21%	64%	71%	64%	71%	68%	68%	68%
PASI ≤5 AO	0	21%	64%	71%	68%	83%	81%	80%	80%
PASI ≤2 LOCF	0	14%	46%	61%	46%	50%	50%	50%	43%
PASI ≤2 AO	0	14%	46%	61%	48%	57%	62%	60%	50%
PASI =0 LOCF	0	14%	36%	43%	32%	36%	39%	39%	25%
PASI =0 AO	0	14%	36%	43%	32%	39%	48%	45%	25%

FIGURE 2 Evolution of the absolute PASI response over time. AO, as observed; LOCF, last observation carried forward; PASI, psoriasis area and severity index.



	Month 0 (n=28)	Month 1 (n=28)	Month 4 (n=28)	Month 7 (n=28)	Month 13 (n=25)	Month 19 (n=23)	Month 25 (n=21)	Month 31 (n=20)	Month 37 (n=20)
PASI 75 LOCF	0	36%	71%	82%	79%	79%	79%	79%	75%
PASI 75 AO	0	36%	71%	82%	84%	91%	95%	95%	90%
PASI 90 LOCF	0	18%	57%	75%	61%	68%	64%	64%	61%
PASI 90 AO	0	18%	57%	75%	64%	78%	81%	80%	75%
PASI 100 LOCF	0	14%	36%	43%	32%	36%	39%	39%	25%
PASI 100 AO	0	14%	36%	43%	32%	39%	48%	45%	25%

FIGURE 3 Evolution of the relative PASI response over time. AO, as observed; LOCF, last observation carried forward; PASI, psoriasis area and severity index.

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with 22 patients of whom 68.2% and 86.3% reached, after 28 weeks, PASI90 and PASI75 responses, respectively.[10] Our patients showed a rapid improvement, quite significant after 16 weeks of UST follow-up, with 16 patients (57%) and 20 patients (71%) achieving PASI90 and PASI75, respectively. The most significant improvement was achieved within the first 7 months. From then on, PASI score remained virtually unchanged.

Lack of an adequate response was the main reason for UST discontinuance in our study (5 out of 28 patients). In the Italian series, only 2/22 patients interrupted therapy due to lack of efficacy, while four patients discontinued it due to clinical remission.[10]

The safety analysis in our study only showed three nondrug-related SAE. The adverse events collected in most cases[6–8,10,12–14] agree with this safe profile.

Limitations are the retrospective and multicenter design of the study, and the limited number of patients, mainly due to the low prevalence of this clinical form of psoriasis. Strengths of our study are the long follow-up and treatment time with UST (148 weeks), the use of both relative and absolute PASI to evaluate effectiveness, and the analysis of the data using both "as observed" and "intention-to-treat LOCF" methods.

Based on our study, we conclude that UST is a fast, highly effective, and safe alternative for the treatment of EP. Prospective comparative clinical trials are needed to assess the safest and most efficacious therapies to carry out an individualised treatment strategy for EP in daily practice.

AUTHOR CONTRIBUTIONS

Clara Plana, Maria J. Concha-Garzón, Vicen C. Rocamora, Ofelia Baniandrés, Rosa Feltes, Jose L. López-Estebaranz, Joan Garcías-Ladaria, Jose-Manuel Carrascosa, Eva Vilarrasa, Caridad Soria, Belen Navajas, Mar Llamas-Velasco and Esteban Dauden have contributed to conceptualisation, data curation, funding acquisition, investigation, resources, validation, writing review and editing. Clara Plana, Maria J. Concha-Garzón, Vicen C. Rocamora, Ofelia Baniandrés, Rosa Feltes, Jose L. López-Estebaranz, Joan Garcías-Ladaria, Jose-Manuel Carrascosa, Eva Vilarrasa, Caridad Soria, Belen Navajas, Mar Llamas-Velasco and Esteban Dauden have contributed to supervision, validation, project administration. Clara Plana and Esteban Dauden have contributed to the writing of the manuscript and perform the formal analysis. All the authors have reviewed and accepted the submitted version of the manuscript.

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CONFLICTS OF INTEREST STATEMENT

Vicen C. Rocamora: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, with the following pharmaceutical companies: Abbvie, Almirall, Amgen, Celgene, Janssen-Cilag, Leo Pharma, Lilly, Novartis, Pfizer, UCB. Ofelia Baniandrés: Has participated in Advisory Boards, consultant, participation in clinical trials, honorarium for speaking from Abbvie, Janssen-Cilag, Pfizer, Celgene, Novartis, UCB, Leo Pharma, Almirall and Lilly. Rosa Feltes: Has participated in clinical trials for drug development of Novartis, Lilly, UCB, Jannsen-Cilag, Almirall, Pfizer, Leo Pharma and Abbvie. José L. López-Estebaranz: Served as a consultant in clinical trials and/or received speaking fees from Almirall, Janssen, Leo-Pharma, Lilly, Abbvie, Bioderma, Galderma, UCB, Novartis, Pierre-Fabre, Bioscience, Invasix and Isdin. Juan Garcías-Ladaria: Advisory Board member, participation in clinical trial, honorarium for speaking, with the following pharmaceutical companies: Janssen-Cilag, Labcorp, Leo Pharma, Novartis. José-Manuel Carrascosa: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, with the following pharmaceutical companies: Abbvie, Almirall, Amgen, Celgene, Janssen-Cilag, Leo Pharma, Lilly, Novartis, Pfizer, UCB, Brystol-Myers and Boehringer-Ingelheim. Eva Vilarrasa: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, with the following pharmaceutical companies: Abbvie, Almirall, Amgen, Bristol-Myers, Boheringer-Ingelheim, Celgene, Janssen-Cilag, Leo Pharma, Lilly, MSD-Schering-Plough, Novartis, Pfizer, Sandoz, and UCB. Caridad Soria: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, with the following pharmaceutical companies: Abbvie, Almirall, Amgen, Celgene, Janssen-Cilag, Leo Pharma, Lilly, MSD-Schering-Plough, Novartis, Pfizer, and UCB. Mar Llamas-Velasco: Advisory board member, consultant, research support, participation in clinical trials and honorary for speaking, with the following pharmaceutical companies: Abbvie, Almirall, Amgen, Boehringer, Celgene, Janssen, Leo, Lilly, Novartis and UCB. Esteban Dauden: Advisory Board member, consultant, grants, research support, participation in clinical trials, honorarium for speaking, research support, with the following pharmaceutical companies: Abbvie/Abbott, Almirall, Amgen-Celgene, Janssen-Cilag, Leo-Pharma, Novartis, Pfizer, MSD-Schering-Plough, Lilly, UCB, Brystol-Myers and Boehringer-Ingelheim. The remaining authors declare no conflict of interest.

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DATA AVAILABILITY STATEMENT

The raw data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

The study has been carried out in accordance with the ethical principles of the Declaration of Helsinki. Reviewed and approved by the Ethics Committee of Hospital Universitario de la Princesa (09/05/2022).

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