ACTAS Dermo-Sifiliográficas 116 (2025) T21–T30

ACTAS Dermo-Sifiliográficas

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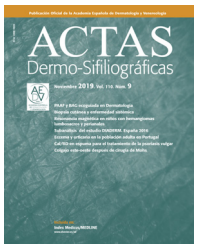

ORIGINAL ARTICLE

[Translated article] Measurement Assessment of Minimal Disease Activity in Psoriasis in Spain: A National Cross-Sectional Study

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Received 9 October 2023; accepted 5 May 2024
Available online 9 October 2024

DOI of original article:
https://doi.org/10.1016/j.ad.2024.05.022
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https://doi.org/10.1016/j.ad.2024.10.009
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KEYWORDS
Psoriasis;
Minimal Disease Activity;
Psoriasis severity;
Therapeutic goal

Abstract
Introduction: In 2017, the Spanish Academy of Dermatology and Venereology Psoriasis Working Group (PWG) designed the Minimal Disease Activity (MDA) criteria to determine the level of disease activity. We hereby present the results of an observational, cross-sectional, multicenter study of the nationwide application of these criteria.
Material and methods: We conducted a non-randomized sampling, stratified to achieve autonomic and provincial representation of consecutive patients with psoriasis (Ps) vulgaris without active arthritis. A total of 830 patients were included: 493 men (59.5%), with a mean age of 51.4 years (SD, 14.2), from all autonomous regions of Spain (except for Ceuta and Melilla) and 44 (88%) out of the 50 provinces. A questionnaire was obtained with demographic data, DLQI, subjective assessment—on a scale from 0 to 10—of itching, erythema, desquamation, visibility, and the patients' PASI and BSA.
Results: More than 50% failed to meet the MDA criteria (491; 59.2%), with significant differences being reported by region, sex, and age. Additionally, significant differences were reported based on the therapy used (P<.001). The use of biological therapies was associated with higher MDA compliance compared to other therapies (59.4% vs 23.3%). No differences were reported among various biological therapies.
Conclusions: The overall rate of MDA compliance is low, with differences being based on geographic location, sex, age, and drug used, yet none of these factors separately justify them.
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PALABRAS CLAVE
Psoriasis;
Actividad Mínima de Enfermedad;
Gravedad psoriasis;
Objetivo terapéutico

Valoración de la medida de Actividad Mínima de Enfermedad en Psoriasis en España: estudio transversal nacional

Resumen
Introducción: El Grupo de Psoriasis de la Academia Española de Dermatología y Venereología (GPs) diseño en 2017 la medida Actividad Mínima de Enfermedad en Psoriasis (AME). Se presentan los resultados de un estudio observacional, transversal y multicéntrico de la aplicación de esta escala a nivel nacional.
Material y métodos: Se realizó un muestreo no aleatorizado, estratificado para alcanzar representación autonómica y provincial, de pacientes consecutivos con psoriasis (Ps) vulgar sin artritis activa. Se incluyeron 830 pacientes: 493 eran varones (59,5%), con una edad media de 51,4 años (DE = 14,2), de todas las autonomías del país (excepto Ceuta y Melilla) y 44 (88%) de las 50 provincias. Se obtuvo un cuestionario recogiendo datos demográficos, DLQI, valoración subjetiva en escalas de 0 a 10 de picor, eritema, descamación y visibilidad; y el PASI y el BSA del paciente.
Resultados: Más de la mitad no cumplían criterio de AME (491; 59,2%), con diferencia significativa entre regiones, por el sexo y por la edad. También había diferencias según el tratamiento realizado (p < 0,001). El uso de un medicamento biológico se asoció a un mayor cumplimiento AME frente al uso de otro tipo de medicamentos (59,4 vs. 23,3%). No se observaron diferencias entre los tratamientos biológicos.
Conclusiones: El porcentaje global de cumplimiento AME es bajo, con diferencias por la localización geográfica, el sexo, la edad y el fármaco utilizado, si bien ninguno de esos factores por separado las justifica.
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Introduction

According to the World Health Organization (WHO), psoriasis (Ps) is a chronic, non-communicable, painful, disfiguring, and disabling disease, with no cure and a significant negative impact on the patient's quality of life (QoL).[1]

Despite therapeutic advances, some patients do not achieve complete clearance of skin signs or continue to have other issues that negatively affect their QoL.[2] This, along with differing expectations and priorities between dermatologists and patients in disease management,[3] requires changes to adjust treatment on an individual basis, objectively measuring results[4,5] to achieve a holistic approach to disease management.[6]

Disease severity measures can be objective (Psoriasis Activity Skin Index [PASI], Body Surface Area [BSA], or percentage of skin affected; Physician Global Assessment [PGA]), or subjective, evaluated by the patient

Table 1 Demographic data.

Total patients	N	%
N	830	100.0
Autonomous community	N	%
Andalusia	97	11.8
Aragón	100	12.1
Asturias	49	5.9
Balearic Islands	4	0.5
Canary Islands	53	6.4
Cantabria	28	3.4
Castile and León	58	7.0
Castile-La Mancha	14	1.7
Catalonia	124	15.0
Valencia	50	6.1
Extremadura	10	1.2
Galicia	49	5.9
Madrid	96	11.6
Murcia	53	6.4
Navarre	10	1.2
Basque Country	25	3.0
Rioja	5	0.6
Sex	N	%
Male	493	59.5
Female	336	40.5
Age in years, mean (SD)	51.4 (14.2)	

(Dermatology Life Quality Index [DLQI]). However, each of these indices has intrinsic limitations, as previously mentioned.[7]

In 2017, the Psoriasis Working Group (PWG) of the Spanish Academy of Dermatology and Venereology embarked on a project to create a measure that jointly assessed the impact of the disease between patient and dermatologist, which gave birth to the Minimal Disease Activity in Psoriasis (MDA).[7] MDA includes the dermatologist's evaluation of the BSA, presence or absence of special localization, and the exclusion of arthritis. The patient scores the DLQI and quantifies the intensity of itching (0-10), erythema (0-10), scaling (0-10), and visibility (0-10). MDA is met in the absence of active arthritis plus 3 of the following items: itching $\leq$ 1/10; scaling $\leq$ 2/10; redness $\leq$ 2/10; visibility $\leq$ 2/10; BSA $\leq$ 2; DLQI $\leq$ 2, and no lesions in special locations.

The objective of our study was to describe the MDA situation in the routine clinical practice in Spain.

Materials and methods

We conducted a national, observational, cross-sectional, and multicenter study. Each region provided information from 10 dermatologists through one coordinator. Participant dermatologists consecutively collected data from 5 patients with plaque Ps and no active arthritis. Informed consent, epidemiological and clinical data (sex, age, therapeutic status, and drug used; presence or absence of special location; and confirmation of the absence of active arthritis), PASI, BSA, DLQI, as well as patient-reported intensity of itching, erythema, scaling, and visibility were collected.

Data were entered by each regional coordinator into a web platform specifically designed by the research unit of AEDV, responsible for the analysis.

A descriptive analysis was conducted where continuous variables were expressed as mean and standard deviation (SD), median, first and third quartile, and maximum and minimum. Differences were evaluated using the Student's t-test or the Mann-Whitney U test. Qualitative variables were expressed as absolute and relative frequencies, and differences were evaluated using the chi-square test. A smoothed line chart of the probability of not meeting MDA criteria based on PASI was created to determine an optimal cut-off point through logistic regression. Finally, multivariable logistic regression adjusted by region was used to determine the association between meeting MDA criteria and different epidemiological and clinical characteristics.

The study was approved by Hospital Universitario de Gran Canaria Dr. Negrín Ethics Committee of (2022-299-1). All patients gave their consent to participate in the study.

Results

A total of 18 coordinators and 180 dermatologists from across Spain participated in the study collecting data from 830 patients with vulgar Ps and without active arthritis. Data were obtained from 17 autonomous communities—except for Ceuta and Melilla—and 44 of the 50 provinces, with differences across regions: Catalonia 124 patients, maximum;

Table 2 Global clinical description.

	N	Mean	SD	Median	1st Quartile	3rd Quartile	Min	Max
BSA (0-100)	827	4.7	7.6	2.0	0.2	6.0	0.0	58.0
PASI (0-72)	826	3.5	5.2	1.8	0.2	4.5	0.0	44.1
DLQI (0-30)	821	3.5	4.6	2.0	0.0	5.0	0.0	24.0
Itch (0-10)	829	2.9	3.2	2.0	0.0	5.0	0.0	10.0
Scaling (0-10)	828	3.2	3.2	2.0	0.0	6.0	0.0	10.0
Erythema (0-10)	829	3.1	3.2	2.0	0.0	6.0	0.0	10.0
Visibility (0-10)	829	3.3	3.5	2.0	0.0	6.0	0.0	10.0

SD: standard deviation.

Table 3 Values of parameters for MDA criteria.

Parameter	N	Percentage
Active arthritis		
No	830	100.0
Involvement of special locations		
No	511	61.7
Yes	317	38.3
Itching ≤ 1/10		
No	433	52.2
Yes	396	47.8
Scaling ≤ 2/10		
No	382	46.1
Yes	446	53.9
Redness ≤ 2/10		
No	380	45.8
Yes	449	54.2
Visibility ≤ 2/10		
No	372	44.9
Yes	457	55.1
BSA ≤ 2		
No	369	44.6
Yes	458	55.4
DLQI ≤ 2		
No	337	41.0
Yes	484	59.0

Balearic Islands, 4 patients, minimum). Of these, 493 were men (59.5%) with a mean age of 51.4 years (SD, 14.2 years) (Table 1).

The mean disease severity values as measured by dermatologist and patient were: BSA, 4.7; PASI, 3.5; DLQI, 3.5; itching, 2.9; scaling, 3.2; erythema, 3.1; visibility, 3.3 (Table 2).

A total of 61.7% had no lesions in special locations, 47.8% had itching ≤ 1/10; 53.9%, scaling ≤ 2/10; 54.2%, redness ≤ 2/10; 55.1%, visibility ≤ 2/10; 55.4%, BSA ≤ 2; and 59%, DLQI ≤ 2 (Table 3).

More than half of the patients (491; 59.2%) did not meet MDA criteria, and we found significant differences across regions (highest frequency in Asturias: 98%; lowest in Catalonia: 37.1%) ($p < 0.001$) (Graph 1).

MDA compliance showed significant differences by sex and age. Men had a higher percentage of MDA compliance (222 patients, 45.0% vs 117 women, 34.8%) ($p < 0.003$), as did older patients (mean age, 52.9 years; SD, 14.3) vs younger patients (50.4 years; SD, 14) ($p < 0.013$). Additionally, differences in compliance by sex were seen across regions (Graph 1).

Additionally, differences were reported in MDA compliance based on treatment ($p < 0.001$). Biological therapy was associated with higher MDA compliance vs non-biological therapy (59.4% vs 23.3%). Although no differences were seen between different biological therapies ($p = 0.108$), significant differences were found vs non-biological therapies ($p < 0.001$) (Table 4).

Subjective symptoms reported by patients—itching, scaling, erythema, visibility—were the main reason for not meeting MDA, mainly itching > 1 (72.5%) (Supplementary data).

A total of 23% of patients with PASI: 0 (45, 22.3%) did not meet MDA criteria (Table 5). For every unit increase in PASI, the risk of not meeting MDA criteria almost doubled (regardless of treatment); OR, 1.84 (95%CI, 1.61-2.10). In this risk, a change in trend is observed from PASI scores of 5 where increments are not as pronounced (Graph 2).

Using a multivariable logistic model, we found that the probability of meeting/not meeting MDA criteria involved the simultaneous use of biological drugs, PASI, age, sex, and geographic region. None of these factors alone—not even the use of biological drugs—explained the differences found (Table 6).

The data can be accessed through the viewer: https://aedv.es/grupos-de-trabajo/psoriasis/visualizador-de-casos-de-proyecto-ame/

Discussion

Disease control by applying AME criteria: global and regional perspectives

Although the mean values of PASI and BSA show that the patients included had mild disease or were well controlled (4) (Table 2), compliance to MDA is very low: 491 patients (59.2%) do not meet the MDA criteria.

Differences across regions are also clear (Graph 1). Catalonia is the region with the highest MDA adherence, although more than a third of patients (37.1%) do not meet MDA. The fact that a higher percentage of patients on biological therapies was found in this community for our study purposes could favor greater adherence. Access to certain

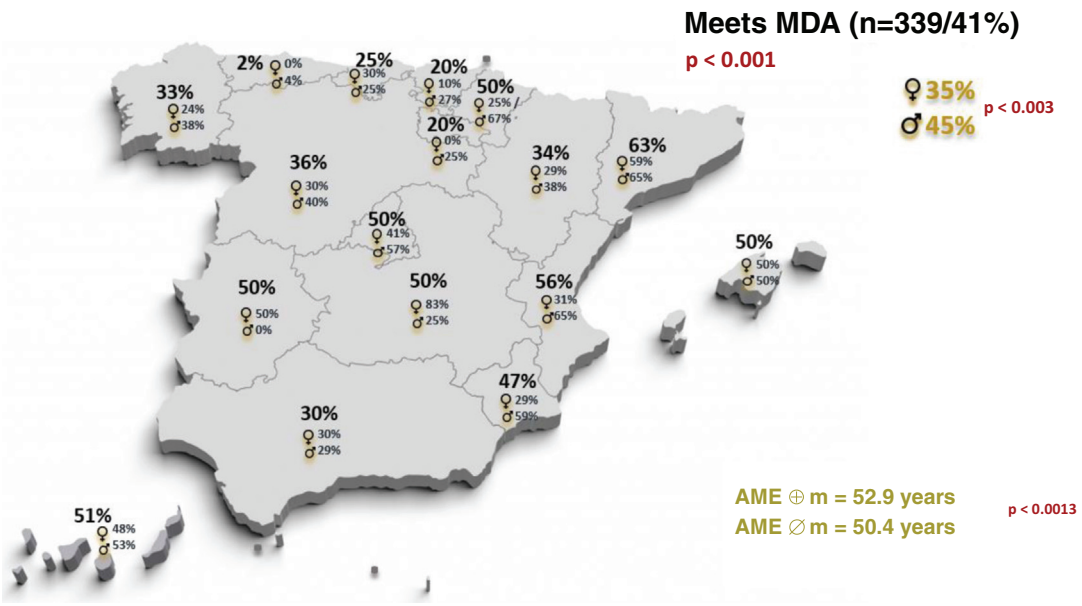

Figure 1 Adherence to MDA by regions and gender.

Table 4 MDA compliance and antipsoriatic treatment.

	Does not meet MDA	%	Meets MDA	%	Total (N)	% (per column)
Type of therapy						
None	45	80.4	11	19.6	56	6.8
Topicals†	153	88.4	20	11.6	173	20.9
Classic systemic	85	62.5	51	37.5	136	16.4
Biologics	167	40.6	244	59.4	411	49.6
Orals (apremilast/fumarates/tofacitinib)	21	61.8	13	38.2	34	4.1
Phototherapy	18	100.0			18	2.2
*p < 0.001						
Non-Biologics vs Biologics						
Non-biologics	277	76.7	84	23.3	361	46.8
Biologics	167	40.6	244	59.4	411	53.2
**p < 0.001	277	76.7	84	23.3	361	46.8
Biological therapies						
Anti-TNF	71	47.7	78	52.3	149	36.3
Anti-IL-17	36	41.4	51	58.6	87	21.2
Anti-IL-12/23	21	32.8	43	67.2	64	15.6
Anti-IL-23	39	35.1	72	64.9	111	27.0
***p < 0.108 (n.s.)						
Non-biological therapies						
NONE	45	80.4	11	19.6	56	13.4
Topical (alone) †	153	88.4	20	11.6	173	41.4
Methotrexate	61	60.4	40	39.6	101	24.2
Dimethyl fumarate	3	75.0	1	25.0	4	1.0
Acitretin	18	66.7	9	33.3	27	6.5
Cyclosporine	6	75.0	2	25.0	8	1.9
Phototherapy	18	100.0			18	4.3
Apremilast	17	58.6	12	41.4	29	6.9
Other (tofacitinib)	2	100.0			2	0.5
****p < 0.001						

† Corticosteroid or calcipotriol + betamethasone.

Table 5 MDA compliance based on PASI score.

	Meets MDA			
	No		Yes	
	N	%	N	%
PASI = 0	45	22.73	153	77.27
PASI < 1	84	27.80	218	72.20
PASI < 2	152	35.00	282	65.00
PASI < 3	219	41.00	315	59.00
PASI < 4	273	45.60	326	54.40
PASI < 5	303	47.80	331	52.20

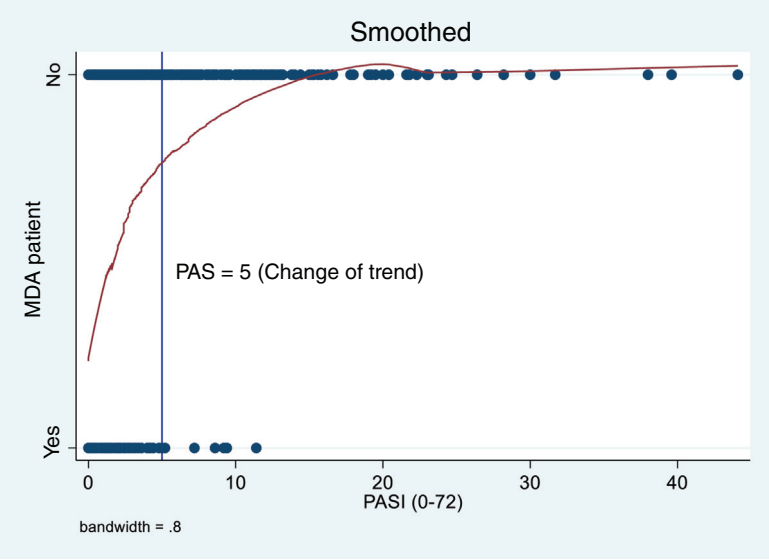

Figure 2 Probability of not meeting MDA criteria based on PASI score.

biological drugs is a known factor, as some regions allow the use of any biological drug as a first-line therapy while others require biosimilars of anti-TNF initially or even a specific sequence.[8]

However, it is not only the greater use of biologicals that justifies this regional difference, as we know that, besides biological use, age, gender, and patients' PASI scores also influence the outcomes. When we include these factors, regional differences persist, although they tend to decrease (but not completely disappear). As seen in Table 6, the significant differences reported across all factors—simultaneously—imply that all are associated, and the use of biologicals alone cannot fully explain the existing differences.

Adherence to MDA by sex and age

Patients' treatment preferences play an important role in consultations. Age seems to influence therapy choices, both for topical treatments and biologicals, with younger people showing more interest in the potential benefits of these therapies.[9] However, we found that older patients are more likely to meet the MDA, which is consistent with the worse quality of life (QoL) scores given by younger individuals,[10] though this contrasts with other studies where older patients with skin conditions report worse QoL due to additional health issues.[11]

In our study, we also found that men are more likely to meet the MDA vs women (Graph 1). Other studies have found a gender distinction favorable to women regarding biological drug prescriptions[12]; women also seem to experience more itching,[13] greater QoL impact,[14] and more frequent sleep disturbances.[15] These parameters are not typically measured in severity scales—BSA, PGA, PASI—which may underestimate disease severity in certain patient subgroups.

MDA adherence by therapeutic group

Using more effective drugs could be the most determining factor in achieving MDA. In fact, our study found that the use of biological drugs, as opposed to synthetic drugs or phototherapy, is associated with the highest percentage of MDA adherence. Additionally, studies using the Psoriasis Symptoms and Signs Diary (PSSD)—including erythema, itching, pain, and other symptoms—have shown that although various drugs improve these symptoms, no direct comparisons between drugs exist yet to help choose one over another.[16]

Table 6 Multivariable probability model for meeting MDA.

MDA probability	OR	95%CI LL	95%CI UL	p-value
Biological use	2.50	1.65	3.79	0.0000
PASI	0.52	0.43	0.63	0.0000
Age	1.02	1.01	1.03	0.0040
Gender	0.60	0.41	0.88	0.0090
Region				
2	0.91	0.31	2.72	0.8690
3	0.25	0.08	0.77	0.0150
4	0.75	0.25	2.25	0.6120
5	0.01	0.00	0.08	0.0000
7	1.34	0.47	3.81	0.5860
8	0.73	0.25	2.15	0.5660
9	0.70	0.24	2.06	0.5180
10	4.28	1.33	13.76	0.0150
11	2.57	0.86	7.64	0.0900
12	1.98	0.63	6.23	0.2400
13	0.76	0.25	2.27	0.6180
14	0.78	0.28	2.19	0.6420
15	1.23	0.47	3.23	0.6760
16	1.65	0.56	4.89	0.3670
17	0.60	0.15	2.44	0.4780
18	1.75	0.57	5.38	0.3310
19	1.48	0.45	4.84	0.5190

However, we did not observe any significant differences across different biological drugs, possibly due to selection bias in a non-controlled study where we chose the drug we believed had the best success probability for each patient. This could have led to better results in the first group and worse outcomes in the second, resulting in similar effectiveness rates between the 2.[17–20]

It is surprising that no patients on phototherapy achieved MDA, and the high percentages of non-adherence were reported among those who were not on therapy (80.4%) or who were on topical therapies alone (88.4%).

Correlation assessment between PASI and MDA adherence

Although PASI is the standard measure to assess the severity of Ps, it doesn't always correlate directly with patient perception7. PASI was included in the study to compare it with MDA adherence.

PASI as a sole severity measure is imprecise, especially in very mild cases which involve small regions of the skin. In fact, in our study, 23% of patients with PASI 0 did not meet MDA criteria. Additionally, PASI doesn't consider the location of lesions, which we know can significantly impact the patients, such as on nails, folds, genital areas, or palms and soles. Furthermore, PASI is not a linear measure, as 9% to 10% changes in a diseased region of the skin in one location can double the score without any changes being reported in symptoms such as erythema, infiltration, or scaling.[21]

Therefore, it is understandable that up to 28% of patients with PASI < 1 or 35% of patients with PASI < 2 from our study do not meet MDA criteria. However, it is striking that a patient with no Ps lesions (PASI 0) and no psoriatic arthritis either does not meet MDA criteria. This suggests other factors—likely psychological—impacting the feeling of illness or being indicative of some limitations in the specificity of the measurement.

The impact of introducing MDA

The most significant subjective signs of the disease are evaluated in the MDA by the patient, who defines how intense their plaques are, how much they flake, how much they itch, how much they bother, and how visible they are. The importance of these values to the patients is seen in the fact that nearly 70% out of the 491 patients from the study who did not meet the MDA included these subjective symptoms as reasons for non-compliance, with itching being the most frequently cited (72.5%) out of the 4 (see Supplementary data).

In fact, the most bothersome symptom for psoriatic patients is itching, which is present in 60% up to 90% of them,[22] which is consistent with a multicenter study evaluating psychological factors related to psoriasis in which 69.5% of patients reported itching, and nearly 75% of them experienced it chronically.[23]

Ps visibility can lead to social rejection and avoidance behaviors, which significantly affect many patients.[24] In our study, 372 patients did not meet MDA criteria for this reason, reinforcing the idea that including these subjective symptoms—which are not captured by other indices[25,26]—is essential to assessing Ps severity through psychological and social factors that negatively affect the patients' QoL.

MDA is not a sum of PASI, BSA, and DLQI but a global measure of the clinical situation where both the patient and the dermatologist do not see the need for any therapeutic

changes or interventions, providing a different qualitative value.

However, despite its utility in patient management,[27] its use has not yet become widespread, and few reports specify MDA as a therapeutic outcome measure for psoriatic patients.[28]

Study limitations

Being a national study as it is, patient sample is expected to be heterogeneous due to geographic diversity, which can influence the different sensitivities in appreciating the subjective parameters measured by the patient, different perceptions of symptoms based on cultural differences, differences in dermatologist experience (specialized vs general clinic, urban vs rural), different access to more effective drugs,[29] etc.

Although patients were not randomized, they were recruited during routine clinical practice over a short period of time (1-2 days), which may have introduced a participation and selection bias by recruiting the most active participants or those who happened to attend the clinic on those days.

Conclusions

After applying the MDA nationwide, it seems obvious that adherence is relatively low, with significant differences being reported by sex, age, region, type of therapy, and symptoms reported by patients. However, none of these factors alone explained the differences found, and the use of biological drugs alone could not account for the existing differences.

Evaluating MDA vs PASI provides a better approach to patients by allowing them to participate in measuring the severity of their disease, which could lead to a qualitative improvement in the management of these patients.

The use of MDA in routine clinical practice is easy and convenient, and it can improve the quality of psoriatic patient management by including parameters not considered in other widely used severity scales. Therefore, we encourage dermatologists treating psoriatic patients to use MDA as a measure of disease severity and a therapeutic goal.

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Descalzo, M.A.: data analysis, result interpretation, manuscript preparation.

Conflicts of interest

None declared.

Acknowledgments

We wish to thank laboratories Almirall and UCB for their financial and human support in the creation, distribution, and collection of the documentary material from collaborating dermatologists, delivery to each regional coordinator, and for data analysis.

This support was not subject to any requirement or condition regarding the study design, data analysis, result acquisition, or drafting of the manuscript.

Appendix 1. AEDV Psoriasis Working Group in each region led by the corresponding regional coordinator

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Appendix. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ad.2024.10.009.

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