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RESEARCH ARTICLE **OPEN ACCESS**

Characteristics of Clinical Profiles in Psoriatic Arthritis Patients Initiating Ustekinumab by a Dermatologist or Rheumatologist

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Abstract:

Introduction: Psoriatic Arthritis (PsA), an inflammatory disease, is primarily associated with Psoriasis (PsO). This study assesses the collaboration between rheumatologists and dermatologists in PsA diagnosis and disease management. It also describes the clinical profiles of patients with PsA initiating on ustekinumab treatment.

Methods: This is a multicenter, non-interventional, real-world study conducted between 23 June 2017 and 10 April 2020 across 62 sites in France that enrolled patients aged ≥18 years with a confirmed diagnosis of PsA either by a rheumatologist or a dermatologist and who started ustekinumab therapy. The health status and disease activity of the patients were evaluated at baseline, Week 16, and Week 28. The safety of ustekinumab was determined based on adverse events occurring within 90 days following the last ustekinumab administration.

Results: The efficacy set included a total of 203 patients, of whom 133 were managed by rheumatologists and 70 by dermatologists. Painful and swollen joints, dactylitis, and enthesitis were more commonly assessed in patients managed by rheumatologists, while skin lesions and the percentage of body surface area affected by PsO were more frequently assessed among patients managed by dermatologists. Rheumatologist–dermatologist collaboration was documented in 40 patients at Week 16 and 36 patients at Week 28 during follow-up.

Discussion: This study highlights the influence of specialty on clinical decision-making in PsA and reinforces the importance of multidisciplinary care in its management.

Conclusion: Collaboration between rheumatologists and dermatologists for the harmonization of routine practices related to PsA diagnosis and management could be further enhanced.

Keywords: Psoriasis, Psoriatic arthritis, Ustekinumab, Rheumatologist, Dermatologist, Cross-functional collaboration.

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1. INTRODUCTION

Psoriatic Arthritis (PsA), a chronic inflammatory disease, is a type of arthritis that affects individuals with Psoriasis (PsO) [1, 2]. The onset of PsA is predominantly observed between 30 and 50 years of age without any gender disparity [3, 4]. Approximately 1%–3% of the world's population is affected by PsO [5, 6], with almost 40% of patients developing PsA within five to ten years of the disease onset [7-9]. The worldwide prevalence of PsA ranges from 0.3% to 1% [10, 11]. A French real-world study (January 2015–December 2018) estimated the prevalence of PsA at 0.1%, with an incidence of 8.4 per 100,000 people per year [12].

PsA is characterized by multiple systemic manifestations. Joint pain, swelling, and stiffness are the major symptoms of PsA that may lead to disability and decreased work productivity, thereby substantially impacting a patient's quality of life [13, 14]. Additionally, there is an increased risk of comorbidities such as cardiovascular disease, type 2 diabetes, metabolic syndrome, and other inflammatory diseases [15, 16]. An early diagnosis of PsA and prompt treatment initiation are essential to alleviating pain and preventing permanent joint damage and functional disability [13].

The treatment landscape for PsA ranges from traditional nonsteroidal anti-inflammatory drugs to relatively new immunomodulator therapies. The diverse treatment options may support clinicians in addressing the heterogeneity of PsA and providing individualized care. One of the immunomodulator therapies includes ustekinumab, which was approved by the European Medicines Agency (EMA) and the United States Food and Drug Administration (FDA) in 2009 for the treatment of plaque PsO in adult patients [17]. Later in 2013, the indication was extended for the treatment of adults with active PsA by both the EMA and FDA [18]. Multiple randomized controlled trials have established the efficacy of ustekinumab for moderate-to-severe PsO and active PsA [19].

Patients with PsA are typically managed either by a rheumatologist or a dermatologist, depending on whether the symptoms or predominant clinical manifestations are articular or cutaneous [20, 21]. To effectively manage psoriasis, it is necessary to implement diagnosis at an early stage and to prevent and treat any associated comorbidities [22]. However, effective collaboration between the two specialties may help manage the condition better and simultaneously address both articular and cutaneous symptoms. Real-world studies to understand the clinical profiles of patients with PsA and the collaboration between the two specialties involved in PsA management are limited. To address this gap, this study investigates the clinical profiles of patients with PsA managed by either rheumatologists or dermatologists.

2. MATERIALS AND METHODS

2.1. Study Design

This was a prospective, multicenter, observational, non-interventional study conducted between 23 June 2017 and 10 April 2020 across 62 sites in France among adult patients with a confirmed diagnosis of PsA who were initiated on ustekinumab treatment. This study aims to (i) describe the clinical profiles of patients with PsA managed by either rheumatologists or dermatologists, (ii) describe their clinical practices during the diagnosis and follow-up of patients with PsA who have been initiated on ustekinumab treatment, and (iii) assess the collaboration between rheumatologists and dermatologists in PsA diagnosis and disease management. The details of the observation and follow-up period of this descriptive study are presented in Fig. (**S1**). The data were collected at baseline (Week 0) and twice during the observational period, at Week 16 and Week 28.

Following the initial baseline data collection (Week 0), ustekinumab treatment was initiated within the subsequent 4-week period. Subsequent data entries were recorded every 12 weeks (±3 weeks), starting with the second administration of ustekinumab (Week 4) and continuing through Week 28, in alignment with standard clinical practice.

2.2. Study Population

The study included: (i) all patients aged ≥18 years with a confirmed diagnosis of PsA either by a rheumatologist or a dermatologist; (ii) patients starting ustekinumab as the first (biologic-naive patients), second, or third line (biologic-experienced patients) of biologic Disease-Modifying Anti-Rheumatic Drug (bDMARD) therapy; and (iii) patients for whom the first administration of usteki-numab treatment occurred within the four-week period from inclusion assessment. Patients who initiated usteki-numab as a fourth line of therapy or had already been treated with ustekinumab were excluded from the study.

2.3. Data Collected

Data were collected from medical records, hospital reports, clinical databases, administrative forms, laboratory results, prior exposure details, surgery notes, and follow-up documents related to patients' current care.

2.4. Patient-reported Outcomes

The health status and impact of PsA on patients were evaluated at baseline, and at Week 16 and Week 28 using the Visual Analog Scale (VAS), Physician's Global Assessment of Disease Activity–Psoriatic Arthritis (PGA-PsA), and Health Assessment Questionnaire Disability Index (HAQ-DI).

2.5. Safety Evaluation

The safety of ustekinumab (45 mg and 90 mg) was evaluated based on adverse events that occurred within 90 days following the patients' last ustekinumab administration.

2.6. Statistical Analysis

Quantitative variables were described in actual numbers: mean, median, standard deviation, first and third quartiles, and the minimum and maximum range. Qualitative variables were described using actual numbers, frequencies, and percentages for each modality.

3. RESULTS

3.1. Patient Population and Baseline Characteristics

A total of 221 patients participated in this study, of whom 216 patients received at least one ustekinumab injection. Patients who had no post-baseline data endpoint were excluded from the safety analysis set (n=209). From the safety analysis set, patients with at least one post-baseline efficacy parameter were included in the efficacy set (n=203). Among them, 133 patients were managed by rheumatologists and 70 by dermatologists. The mean age of the patients in the efficacy set was 50.8±13.8 years, and the proportion of female patients was 46.3% (n=94). Overall, 34.3% of the patients were overweight, 31.8% were

obese, 31.8% had a Body Mass Index (BMI) in the normal reference range (25.7%–38.6%), and 2.0% were underweight. Most of the baseline characteristics were similar between the patients managed by rheumatologists or dermatologists. The details of baseline characteristics are described in Table **1**.

3.2. Disease History and Type of PsA

The mean time since the first appearance of PsA symptoms was 9.8±9.4 years, and the mean time since the initial diagnosis was 7.0±8.6 years. The most common type of PsA over time was asymmetric oligoarticular arthritis (42.9%), followed by predominant distal interphalangeal joint arthritis (26.6%), symmetrical polyarthritis (20.7%), and axial predominant involvement (19.7%). Other types of PsA, such as mutilating arthritis and undifferentiated PsA, occurred in fewer than 10% of patients (Table **2**).

3.3. Disease History and Type of PsO

Overall, 89.2% of the patients had a history of PsO. The mean time since the first appearance of PsO symptoms was 16.3±12.7 years, and the mean time since the first initial diagnosis was 14.7±12.6 years. The number of patients with PsO managed by rheumatologists, *versus* dermatologists (80.5% *versus* 97.1%). The most common type of PsO was plaque psoriasis (82.8%), followed by nail psoriasis (32.0%). Other types of PsO occurred in fewer than 10% of cases (Table **2**).

3.4. Disease Assessment

The number of painful joints and swollen joints was more often assessed by rheumatologists compared with dermatologists at baseline (94.7% and 96.2% *versus* 72.9% and 68.6%), Week 16 (93.8% and 93.8% *versus* 78.3% and 73.9%), and Week 28 (92.9% and 92.1% *versus* 70.8% and 70.8%). A similar result was observed for dactylitis at baseline (85.7% *versus* 45.7%), Week 16 (85.2% *versus* 53.6%), and Week 28 (80.2% *versus* 49.2%) and for enthesitis at baseline (68.4% *versus* 27.1%), Week 16 (66.4% *versus* 26.1%), and Week 28 (68.3% *versus* 38.5%) (Table **S1**).

3.5. Clinical Features of PsO

3.5.1. Nail Lesion

A total of 74.9% of patients were assessed for nail lesions, with a mean of 3.7±6.6 lesions at baseline. The mean number of nail lesions decreased over time. At Week 16 and Week 28, nail lesions were assessed in 69.5% (with a mean number of 1.8±4.4) and 69.1% (with a mean number of 1.6±4.1) of patients, respectively. The mean number of nail lesions was higher in patients assessed by dermatologists compared to rheumatologists (7.3±7.9 *versus* 2.0±5.1 at baseline, 3.0±5.6 *versus* 1.1±3.4 at Week 16, 3.4±6.0 *versus* 0.7±2.2 at Week 28) (Table **S1**).

Table 1. Baseline and demographic characteristics of patient population.

Patient Characteristics			Rheumatology Cohort (n=133)	Dermatology Cohort (n=70)	Total N=203
Age, years	Non-missing (n)		133	70	203
	Mean (SD)		51.6 (13.0)	49.4 (15.0)	50.8 (13.8)
	Median		52.6	50.6	51.8
Gender, n (%)	Non-missing		133	70	203
	Male		66 (49.6)	43 (61.4)	109 (53.7)
Weight, kg	Non-missing		132	68	200
	Mean (SD)		82.1 (17.8)	76.7 (16.9)	80.3 (17.6)
	Median		80.0	76.0	78.5
BMI (kg/m^2)	Non-missing		131	67	198
	Mean (SD)		29.1 (6.2)	26.4 (4.8)	28.2 (5.9)
	Median		28.0	25.7	26.9
	Underweight, n%		2.0 (1.5)	2.0 (3.0)	4.0 (2.0)
	Normal range, n%		37.0 (28.2)	26.0 (38.8)	63.0 (31.8)
	Overweight, n%		42.0 (32.1)	26 (38.8)	68 (34.3)
	Obese, n%		50.0 (38.2)	13.0 (19.4)	63.0 (31.8)
Long-term illness status	Non-missing		132	70	202
	Yes, n%		128 (97.0)	41 (58.6)	169 (83.7)
Smoking status	Non-missing		132	68	200
	Nonsmokers, n%		61 (46.2)	26 (38.2)	87 (43.5)
	Former smokers, n%		41 (31.1)	15 (22.1)	56 (28.0)
	Smokers, n%		30 (22.7)	27 (39.7)	57 (28.5)
Alcohol consumption	Non-missing		132	68	200
	Yes	Occasionally, n%	42 (87.5)	28 (73.7)	70 (81.4)
		Daily, n%	6 (12.5)	10 (26.3)	16 (18.6)
	No, n%		84 (63.6)	30 (44.1)	114 (57.0)

Abbreviations: BMI: Body mass index; SD: Standard deviation.

Table 2. Disease characteristics of the patient population at baseline.

	Patient Characteristics		Rheumatology Cohort (n = 133)	Dermatology Cohort (n = 70)	Total (N = 203)
Current PsO	Non-missing (n)		133	70	203
	n%		107 (80.5)	68 (97.1)	175 (86.2)
History of PsO	Non-missing (n)		133	70	203
	n%		120 (90.2)	61 (87.1)	181 (89.2)
Time since first appearance of PsO symptoms, years	Non-missing (n)		119	67	186
	Mean (SD)		15.2 (12.2)	18.3 (13.5)	16.3 (12.7)
	Median		11.1	16.9	13.3
Time since first initial PsO diagnosis (years)	Non-missing (n)		119	67	186
	Mean (SD)		13.8 (12.5)	16.3 (12.7)	14.7 (12.6)
	Median		9.0	13.7	11.2
Types of PsO	Plaque psoriasis	Non-missing (n)	133	70	203
		n%	102 (76.7)	66 (94.3)	168 (82.8)
	Pustular psoriasis	Non-missing (n)	133	70	203
		n%	15 (11.3)	5 (7.1)	20 (9.9)
	Guttate psoriasis	Non-missing (n)	133	70	203
		n%	9 (6.8)	5 (7.1)	14 (6.9)
	Nail psoriasis	Non-missing (n)	133	70	203
		Nail psoriasis, n%	36 (27.1)	29 (41.4)	65 (32.0)
	Undifferentiated	Non-missing (n)	133	70	203
		n%	5 (3.8)	0 (0.0)	5 (2.5)
	Unknown	Non-missing (n)	133	70	203
		n%	5 (3.8)	0 (0.0)	5 (2.5)
Time since first appearance of PsA, years	Non-missing (n)		132	66	199
	Mean (SD)		9.7 (8.3)	9.9 (11.2)	9.8 (9.4)
	Median		6.8	6.5	6.5
Time since first initial PsA diagnosis, years	Non-missing (n)		133	67	200
	Mean (SD)		6.8 (7.6)	7.3 (10.5)	7.0 (8.6)
	Median		4.0	2.7	3.5
Types of PsA, n (%)	Predominant distal interphalangeal joints arthritis	Non-missing (n)	133	67	200
		n%	30 (22.6)	24 (34.3)	54 (26.6)
	Asymmetric oligoarticular arthritis	Non-missing (n)	133	67	200
		n%	66 (49.6)	21 (30.0)	87 (42.9)
	Symmetrical polyarthritis	Non-missing (n)	133	67	200
		n%	30 (22.6)	12 (17.1)	42 (20.7)
	Mutilant arthritis	Non-missing (n)	133	67	200
		n%	5 (3.8)	0 (0.0)	5 (2.5)
	Axial predominant	Non-missing (n)	133	67	200
		n%	30 (22.6)	10 (14.3)	40 (19.7)
	Undifferentiated	Non-missing (n)	133	67	200
		n%	7 (5.3)	5 (7.1)	12 (5.9)
	Unknown	Non-missing (n)	133	67	200
		n%	4 (3.0)	12 (17.1)	16 (7.9)

Abbreviations: PsA: Psoriatic arthritis; PsO: Psoriasis; SD: Standard deviation.

3.5.2. Body Surface Area (BSA)

The proportion of patients in whom the percentage of BSA was assessed at baseline, Week 16, and Week 28 was 74.4%, 77.7%, and 72.3%, respectively. The percentage of BSA affected by PsO was lower in the patients managed by rheumatologists compared with the patients managed by dermatologists (6.3±8.2 *versus* 20.5±18.3 at baseline, 2.1±3.8 *versus* 3.7±5.8 at Week 16, 1.6±4.0 *versus* 6.5±13.1 at Week 28) (Table **S1**).

3.6. Collaboration between Rheumatologists and Dermatologists for Patient Management

The incidence of collaboration with another specialist at Week 16 and Week 28 was similar between the two cohorts. Collaboration with another specialist was set up for 65 patients (33.0%) at Week 16, and the follow-up for these patients included a collaboration of rheumatologists and dermatologists for 40 patients (61.5%). At Week 28, collaboration with another specialist was set up for 57 patients (29.8%), and the follow-up for these patients included a collaboration of rheumatologists and dermatologists for 36 patients (63.2%).

3.7. Ustekinumab Effectiveness and Safety

Ustekinumab appeared to be effective in 76.5% of overall patients in both the rheumatology and dermatology cohorts who continued treatment until the end of the study. The mean duration of treatment was 207.5±48.8 days for ongoing patients and 83.9±61.8 days for patients who stopped treatment. The mean time from the inclusion visit to the first ustekinumab injection was 7.6±11.0 days. The initial prescribed dose was 45 mg for 152 (74.9%) patients and 90 mg for 51 (25.1%) patients. The proportion of patients receiving ustekinumab as their first, second, and third lines of biotherapy was 52.2%, 34.8%, and 12.9%, respectively. The line of treatment had a statistically significant effect on the duration of treatment, especially during the first 16 weeks, and on treatment discontinuation, which was reduced when ustekinumab was initiated as the first biologic therapy rather than in the second or subsequent lines. Additionally, there was no difference in observed adverse events between the two cohorts.

3.8. Functional Status, Impact of PsA on Patients, and Health Status

Pain and functional ability were assessed by the patients using the VAS and alternative HAQ-DI tools and by the physicians using the PGA-PsA. Based on the VAS, alternative HAQ-DI, and PGA-PsA, disability was more severe in the patients managed by rheumatologists than in the patients managed by dermatologists. There was a gradual reduction in VAS scores from baseline (55.0±24.3) to Week 16 (40.8±28.6) and Week 28 (39.3±28.5). A similar result was observed in the alternate HAQ-DI score at baseline (0.9±0.7), Week 16 (0.7±0.6), and Week 28 (0.7±0.7), and in the PGA-PsA score (reported by the physicians) at baseline (39.5±26.1), Week 16 (25.1±23.8), and Week 28 (22.5±23.1). The alternative HAQ-DI score was worse for the patients managed by rheumatologists compared with the patients managed by dermatologists (1.1±0.7 *versus* 0.6±0.6 at baseline, 0.9±0.7 *versus* 0.3±0.4 at Week 16, and 0.8±0.7 *versus* 0.4±0.5 at Week 28). For PGA-PsA, a similar trend was observed in the rheumatology and dermatology cohorts at baseline (43.0±25.5 *versus* 33.1±26.1), Week 16 (28.0±23.7 *versus* 18.8±22.9), and Week 28 (22.9±22.0 *versus* 21.6±25.5) (Table **3**).

Table 3. Assessment of disease activity by physicians and patients.

Assessment Tool		Study Time Point	Rheumatology Cohort (n=133)	Dermatology Cohort (n=70)	Total (N=203)
VAS scores (Patient)	Baseline	Non-missing	123	65	188
		Mean (SD)	60.0 (22.4)	45.5 (25.2)	55.0 (24.3)
		Median	60.0	50.0	60.0
	Week 16	Non-missing	108	63	170
		Mean (SD)	48.3 (27.4)	27.8 (26.0)	40.8 (28.6)
		Median	50.0	18.0	40.0
	Week 28	Non-missing	106	57	163
		Mean (SD)	44.1 (27.9)	30.4 (27.7)	39.3 (28.5)
		Median	50.0	30.0	40.0
PGA-PsA (Physician)	Baseline	Non-missing	119	65	184
		Mean (SD)	43.0 (25.5)	33.1 (26.1)	39.5 (26.1)
		Median	50.0	32.0	40.0
	Week 16	Non-missing	120	54	174
		Mean (SD)	28.0 (23.7)	18.8 (22.9)	25.1 (23.8)
		Median	20.0	6.5	16.0
	Week 28	Non-missing	118	52	170
		Mean (SD)	22.9 (22.0)	21.6 (25.5)	22.5 (23.1)
		Median	15.0	10.0	14.5

Assessment Tool		Study Time Point	Rheumatology Cohort (n=133)	Dermatology Cohort (n=70)	Total (N=203)
Alternative disability index (HAQ score without adjustment)	Baseline	Non-missing	130	67	197
		Mean (SD)	1.1 (0.7)	0.6 (0.6)	0.9 (0.7)
		Median	0.9	0.5	0.8
	Week 16	Non-missing	114	66	180
		Mean (SD)	0.9 (0.7)	0.3 (0.4)	0.7 (0.6)
		Median	0.8	0.1	0.6
	Week 28	Non-missing	112	58	170
		Mean (SD)	0.8 (0.7)	0.4 (0.5)	0.7 (0.7)
		Median	0.7	0.1	0.5

Abbreviations: HAQ: Health Assessment Questionnaire; PGA-PsA: Physician's Global Assessment of Disease Activity – Psoriatic Arthritis; SD: Standard deviation; VAS: Visual Analog Scale.

4. DISCUSSION

This observational, real-world study identified differences in the profiles of patients with PsA managed by rheumatologists and dermatologists, highlighted limited collaboration between the two specialties in PsA management, and confirmed the effectiveness and safety of ustekinumab. This study contributes to understanding specialty-based clinical decision-making in the management of PsA, particularly in initiating biologic therapy with ustekinumab. This is the first study in France that highlights the limited collaboration between dermatologists and rheumatologists in the management of PsA. It underscores the critical need to harmonize clinical practices and strengthen interdisciplinary collaboration to enhance PsA care and improve patient outcomes.

The demographic profiles of the patients with a confirmed diagnosis of PsA were found to be consistent with those of patients with PsA observed by Stolwijk *et al*. in 2016 [23]. Among the baseline characteristics, body weight and BMI were observed to be higher in the patients of the rheumatology cohort compared with the patients of the dermatology cohort. However, most of the other baseline and demographic characteristics were similar between the two cohorts.

In this study, the assessment of skin lesions and a greater percentage of BSA affected by PsO were more frequent among patients managed by dermatologists, while the assessment of joint involvement was more pronounced among patients managed by rheumatologists. A survey conducted on the perceptions of US patients revealed that rheumatologists were more concerned about joint-related symptoms and that dermatologists were more concerned about skin-related symptoms that may influence disease assessment [21]. A four-year study by Ziob *et al.* also highlighted the need for collaboration among specialties as it improves patient management and outcomes in PsA and PsO [24].

Ustekinumab was established as an effective treatment option for patients with PsA, based on the pain and functional ability scores reported by the patients using the VAS and alternative HAQ-DI. This was further substantiated by the improvement observed in the PGA-PsA evaluation, as performed by the physicians at baseline, Week 16, and Week 28. However, the outcomes reported by the patients were considered more favorable compared to the PGA-PsA reported by the physicians.

Assessment of the specialties involved in the management of PsA confirmed that a low proportion of patients were managed by a multidisciplinary team of specialists or through collaboration with another specialist, further emphasizing the need for stronger cross-specialty coordination. Enhanced collaboration between dermatologists and rheumatologists may lead to more comprehensive assessments, better management of the disease, and improve patient outcomes. Multidisciplinary clinics should be established, and training programs, along with open communication, should be implemented to improve collaboration and optimize patient care for PsA.

5. LIMITATIONS

While interpreting the results of this study, certain limitations must be considered. The unequal distribution of patients (133 treated by rheumatologists *vs*. 70 by dermatologists) with PsA might have led to an overestimation of the difference between the cohorts. Moreover, there are differences in routine clinical practice between the specialties. Additionally, a few of the questionnaires filled out by the patients were incomplete, resulting in missing information. The absence of a control group may have affected the accurate assessment of ustekinumab's effectiveness.

CONCLUSION

The findings of this study revealed distinct differences in how patients with PsA are managed by rheumatologists *versus* dermatologists. These insights shed light on real-world clinical practices and emphasize the importance of aligning diagnostic and treatment approaches across specialties. This pioneering study in France highlights the significance of a multidisciplinary strategy, demonstrating that coordinated efforts between rheumatologists and dermatologists can lead to more comprehensive care and improved patient outcomes. To support this collaboration, the establishment of multidisciplinary clinics is recommended, along with the implementation of targeted training programs and open communication channels. Such initiatives will foster better teamwork and optimize the overall management of PsA.

AUTHORS' CONTRIBUTIONS

The authors confirm their contribution to the paper as follows: P.R., S.C. and D.J.: Conceived and designed the study; S.C.: Collected the data; P.R., S.C. and D.J.: Analyzed and interpreted the results; and P.R., S.C., C.C., L.C. and D.J.: drafted the manuscript. All authors reviewed the results and approved the final version of the manuscript.

LIST OF ABBREVIATIONS

Bdmard	=	Biologic disease-modifying anti-rheumatic drug
BMI	=	Body Mass Index
BSA	=	Body Surface Area
EMA	=	European Medicines Agency
FDA	=	Food and Drug Administration
HAQ-DI	=	Health Assessment Questionnaire Disability Index
PPGA-PsA	=	Physician's Global Assessment of Disease Activity–Psoriatic Arthritis
PsA	=	Psoriatic Arthritis
PsO	=	Psoriasis
SD	=	Standard Deviation
VAS	=	Visual Analog Scale

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study was conducted in compliance with the protocol and regulatory requirements. The study protocol and amendment were reviewed by an independent ethics committee (Comité de protection des personnes; project approval number: 2017/03 – ID RCB: 2016-A01882-49).

HUMAN AND ANIMAL RIGHTS

All procedures performed in studies involving human participants were in accordance with the ethical standards of institutional and/or research committee and with the 1975 Declaration of Helsinki, as revised in 2013.

CONSENT FOR PUBLICATION

The participants were informed orally as well as in writing by the investigators about the nature and purpose of the study and the participation/termination conditions. All participants provided written consent.

STANDARDS OF REPOTING

STROBE guidelines were followed.

AVAILABILITY OF DATA AND MATERIALS

The authors confirm that the data supporting the findings of this research are available within the article.

FUNDING

None.

CONFLICT OF INTEREST

Samira Chaalal and Caren Constantin are employees of Janssen-Cilag during the conduct of this study. Denis Jullien has served as a board member and/or consultant for AbbVie, Almirall, Amgen, Biogen, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Janssen-Cilag, Leo, Lilly, MSD, MEDAC, Novartis, Pfizer, UCB, and Sanofi. He received payment for development of educational presentations, including service on speakers' bureaus, from AbbVie, Celgene, Janssen-Cilag, Leo, Lilly, MEDAC, Novartis, Pfizer, Sanofi and had travel/accommodations expenses covered or reimbursed by AbbVie, Amgen, Biogen, Celgene, Janssen-Cilag, Leo, Lilly, MSD, MEDAC, Novartis, Pfizer, UCB, and Sanofi. Pascal Richette has served as a board member and/or consultant for Janssen-Cilag, AbbVie, Lilly, Pfizer, and UCB.

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SUPPLEMENTARY MATERIAL

Supplementary material is available on the publisher's website along with the published article.

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