

## ORIGINAL ARTICLE

# Secukinumab efficacy in reducing the severity and the psychosocial impact of moderate-to-severe psoriasis as assessed by the Simplified Psoriasis Index: results from the IPSI-PSO study

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## Abstract

**Background** The utility of the Simplified Psoriasis Index (SPI), a recently developed multidomain tool for assessing psoriasis, was investigated in a study assessing response to secukinumab.

**Methods** In an open-label, multicentre study involving 17 French centres, patients with moderate-to-severe plaque psoriasis received secukinumab 300 mg subcutaneously once weekly from baseline to W4, then every 4 weeks until W48. Dermatologist-scored SPI psoriasis severity (proSPI-s) was compared with Psoriasis Area and Severity Index (PASI). Patient self-assessed severity (saSPI-s) and psychosocial impact (SPI-p) were compared with PASI and Dermatology Life Quality Index (DLQI), respectively.

**Results** We included 120 patients (69.2% male; mean age 45.9 years; mean duration of psoriasis 21.6 years). Mean baseline scores were as follows: proSPI-s 24.9, saSPI-s 23.5, PASI 23.1, SPI-p 8.2 and DLQI 13.6. Severity scores achieved by 16 weeks (proSPI-s 2.3, saSPI-s 2.2 and PASI 2.2) were maintained to W52. Reductions in mean psychosocial impact scores were maintained to W52 (SPI-p and DLQI, respectively, 2.1 and 1.5 at W16; 1.5 and 1.9 at W52).

**Conclusions** Decrease of PASI scores in response to secukinumab was closely correlated with proSPI-s, supporting the latter's suitability for assessing response to therapy. Although the correlation between PASI and saSPI-s was slightly weaker, patients were able to complete a valid assessment of their psoriasis independently, and thus potentially remotely. With the added benefit of psychosocial impact assessment (SPI-p), SPI provides a valid tool enabling patients to assess their own psoriasis, remotely if necessary.

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## Conflicts of interest

M.-A. Richard has acted as a consultant for Abbvie, Amgen, Boehringer, Celgene, Lilly, Janssen Cilag, LEO Pharma, Pierre Fabre, Novartis, Pfizer, Sanofi/Regeneron, and UCB and served as an investigator for Abbvie, Bohringer, Galderma, Janssen Cilag, Leo Pharma, Lilly, Novartis, Pierre Fabre and Sanofi/Regeneron. J.-P. Lacour has acted as an investigator receiving grants from AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, Galderma, Janssen, LEO Pharma, Lilly, MSD, Novartis, Pfizer, Regeneron and Roche; as a consultant receiving honoraria from Celgene, Galderma, LEO Pharma, Lilly, Novartis, Regeneron, Roche and Sanofi; and as a speaker receiving honoraria from AbbVie,

[Correction added on 29 October 2020, after first online publication: In the Abstract and Figure 4b label, 'saSPI-p 8.2' and '(b) saSPI-s' have been corrected to 'SPI-p 8.2' and '(b) SPI-p' respectively]

BMS, Celgene, Galderma, LEO Pharma, Lilly, Novartis, Roche and Sanofi. M.-P. Konstantinou has acted as an investigator for AbbVie, Amgen, BMS, Boehringer Ingelheim, Celgene, UCB, Janssen, LEO Pharma, Lilly, MSD, Novartis, Pfizer, Regeneron and Roche, and a speaker for Novartis, Lilly, Janssen and AbbVie. M. Ruer-Mulard has acted as an investigator for Novartis, Lilly, Janssen, LEO Pharma, AbbVie and Avene; as a consultant for Janssen and Sanofi; and as a speaker for Novartis, Lilly, Janssen and AbbVie. P. Joly has acted as a consultant for Novartis Lilly, Janssen and Celgene. E. Mahé has paid activities as a consultant, advisor or speaker for AbbVie, Boehringer-Ingelheim, Janssen, Celgene, LEO Pharma, Lilly, Amgen, AstraZeneca, Novartis and Pfizer. S. Aractingi has acted as a consultant for Novartis and a speaker receiving honoraria from Novartis and Lilly. B. Pelvet is an employee of Novartis Pharma. M. Augustin is an employee of Novartis Pharma. P. Auquier and R.J.G. Chalmers have no conflict of interest.

## Funding source

NOVARTIS SAS.

### What's already known about this topic?

- The Psoriasis Area and Severity Index (PASI) is widely required by funding bodies for decisions on access to biologic therapy but has been repeatedly criticized.
- The Simplified Psoriasis Index (SPI) is a recently developed alternative psoriasis measurement tool which assesses both psoriasis severity and its psychosocial impact.
- Secukinumab has been shown to be an effective treatment for moderate-to-severe psoriasis.

### What does this study add?

- Reductions in PASI scores were closely paralleled by those of the severity domain of SPI.
- Efficacy of secukinumab was demonstrated for each of the 10 body sites scored by SPI.
- The severity and psychosocial impact domains of proSPI correlated well with PASI and the Dermatology Life Quality Index, respectively.
- The good correlation between physicians' (proSPI-s) and patients' (saSPI-s) scores opens the possibility of using saSPI to monitor patients remotely.

## Introduction

Chronic plaque psoriasis is an inflammatory immune-mediated disease manifesting as disfiguring scaly red patches on the skin, often accompanied by itching or soreness. It can have a profound impact on quality of life including a patient's emotional, social, occupational and physical functioning.<sup>1</sup> Although there is currently no cure for psoriasis, the disease may respond to a wide range of treatment strategies.

Secukinumab, a monoclonal anti-IL-17A antibody, has been shown to be an effective treatment for moderate-to-severe psoriasis. Subcutaneous administration of 300 mg per week during the induction phase (first month) and 300 mg per month thereafter has proven to be the optimal regimen.<sup>2-5</sup>

In recent years, most studies of interventions for psoriasis have used the Psoriasis Area and Severity Index (PASI) for assessing psoriasis severity and its response to treatment,<sup>6,7</sup> together with the Dermatology Life Quality Index (DLQI) for assessing changes in the functional and psychological impact of psoriasis with treatment. The PASI has well-known limitations,<sup>8,9</sup> notably that it fails to take into account the added impact of psoriasis affecting functionally or psychosocially important body sites and how this may affect patients' well-being.<sup>1</sup> The DLQI, which is not psoriasis specific, contains a number of components which are irrelevant to many psoriasis patients, and the upper half of its range (16-30) is infrequently used.

The Simplified Psoriasis Index (SPI), recently developed in Britain, is a holistic psoriasis assessment instrument which incorporates separate domains for current severity (SPI-s), psychosocial impact (SPI-p) and past history and interventions (SPI-i), as shown in Fig. 1.<sup>10,11</sup> It is available in complementary versions either for completion by healthcare professionals (proSPI) or for self-assessment by patients (saSPI); the only difference between the two is that technical language is avoided in the latter. The current severity domain (SPI-s) accords extra weight to certain functionally or psychosocially important body sites (scalp, face, anogenital area, hands, feet, with nail psoriasis contributing to scores for the latter two sites if appropriate). Good correlation between PASI and both versions of SPI-s and between DLQI and SPI-p was demonstrated in a study of 100 psoriasis patients using the original English version of SPI,<sup>10</sup> and, more recently, in a study using a version translated into Thai.<sup>11</sup> A further study by the same investigators confirmed the responsiveness of SPI-s to change.<sup>12</sup>

The current severity domain of SPI (SPI-s) consists of two components: psoriasis extent (part 1A) for which the extent of psoriasis involving 10 unequally sized body sites (Fig. 1) is

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**Simplified Psoriasis Index Professional assessment (proSPI)**

DATE: \_\_\_\_\_

LABEL or Record no: \_\_\_\_\_ Sex: \_\_\_\_\_

First name: \_\_\_\_\_

Surname: \_\_\_\_\_

**PART 1A** Circle the option which most closely describes the current extent of psoriasis in each body area

0	±	+
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0 clear or minimal with no more than a few scattered thin plaques (0)  
 ± obvious but still leaving plenty of normal skin (0.5)  
 + widespread and involving much of the affected area (1.0)<sup>§</sup>

§ Please note that this is not the same as percentage body surface area (BSA) involvement: the extent score takes into account how dispersed the plaques are

1 Scalp & hairline	0	½	1
2 Face, neck & ears	0	±	+
3 Arms & ampits	0	±	+
4 Hands, fingers & fingernails*	0	±	+
5 Chest & abdomen (stomach)	0	±	+
6 Back & shoulders	0	±	+
7 Anogenital area	0	±	+
8 Buttocks & thighs	0	±	+
9 Knees, lower legs & ankles	0	±	+
10 Feet, toes & toenails*	0	±	+

\* score severe dystrophy of ≥ 2 nails as 0.5 and ≥ 6 nails as 1.0  
 Total extent score: maximum 10 points

**B PART 1B** Select the option which best describes the current average severity of psoriasis. This should take into account all affected areas identified above, not just the worst areas. Please refer to photographic severity key if available.

0	1	2	3	4	5
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0 Essentially clear: with faint erythema or residual pigmentation only  
 1 Mild: erythema and/or scale with focal slight palpable thickening  
 2 Mild-to-moderate: erythema and/or scale with majority of affected skin palpably thickened  
 3 Moderate: erythema and/or scale and/or skin thickening  
 4 Marked: erythema and/or scale and/or skin thickening  
 5 Intensely inflamed skin: with or without pustulation

Average severity score : maximum 5 points

Professionally-assessed current extent and severity score (proSPI-s) = 1A x 1B (max. 50)

**PART 2** Ask patient to mark the line below in response to the question: "How much is your psoriasis affecting you in your day-to-day life today?"

0 1 2 3 4 5 6 7 8 9 10

Guide: 0 = my psoriasis is not affecting me at all  
 5 = my psoriasis is affecting me quite a lot  
 10 = my psoriasis is affecting me very much (I could not imagine it affecting me more)

**PART 3** This part forms a summary record of the patient's psoriasis history and of interventions received. If the information from the previous assessment is known and has not changed since, enter U (unchanged) in the box to the right ⇒

About the patient's psoriasis Give one point for each statement which is true

The patient has had psoriasis for at least 10 years

The patient's psoriasis first developed before the age of 10 or has been present for more than 20 years

The patient has had erythrodermic or generalised pustular psoriasis

The patient has confirmed psoriatic arthritis

About the patient's treatment How many different psoriasis treatments (other than topicals) has the patient received?

Ultraviolet phototherapy (UVB and/or PUVA) maximum 1 point

Systemic psoriasis treatments (1 point for each different active agent) maximum 5 points

Summary of systemic treatments received (optional) \* Enter all systemic agents received to date. If a treatment is not listed, add it in one of the blank boxes. The list of agents may be modified to reflect local availability or the introduction of new treatments.

SEVERITY (0-50) PSYCHOSOCIAL (0-10) INTERVENTION (0-10)

**Figure 1** Simplified Psoriasis Index (SPI) version for completion by healthcare professionals (proSPI)\*. \*showing updated English version with modifications to PART 3: the systemic agents to be displayed can be preselected from drop-down lists to reflect past and current practice in each department before the proforms are printed for distribution; the English language versions of both proSPI and saSPI are freely available for download as supplementary files (<https://globalsporiasisatlas.org/resources>).

scored on a 3-point scale: 0, absent or minimal; 0.5, 'noticeable'; or 1, extensive, and overall average plaque severity (part 1B), which is scored on a scale of 0 (essentially clear) to 5 (intensely inflamed skin). SPI-s is the product of the scores for parts 1A (maximum 10) and 1B (maximum 5), giving a maximum current severity score of 50.

The psychosocial impact score (SPI-p) is marked by the patient on a 10 cm visual analogue scale and converted to an 11-point Likert scale from 0 ('My psoriasis is not affecting me at all') to 10 ('My psoriasis is affecting me very much – I could not imagine it affecting me more'). The historical course and interventions score (SPI-i) is assessed by 10 questions, four relating to disease course and six to previous interventions received.<sup>12</sup> It is not discussed further in this report. Both versions of SPI have recently been translated into French and linguistically validated using a well-established procedure (Figs S1 and S2, Supporting Information).<sup>13</sup>

The primary objective of the present study was to compare proSPI with PASI as a tool for assessing psoriasis severity in patients treated with secukinumab. Secondary objectives were to

compare patient self-assessments (saSPI-s and SPI-p) with PASI and DLQI, respectively.

**Methods**

**Diagnosis and main criteria for inclusion**

Patients aged ≥18 were eligible for inclusion if they had had moderate-to-severe chronic plaque psoriasis for at least 6 months prior to the screening visit, were considered suitable for systemic therapy and met the following criteria at baseline: PASI ≥12, Body Surface Area (BSA) ≥10 and Investigator's Global Assessment (IGA) modified 2011<sup>14</sup> ≥3. Furthermore, they were required to understand and communicate with the investigator and to be able to comply with the study protocol. The validated French translations of PASI, DLQI and SPI were used for the study.

The study protocol and all amendments were reviewed by the Independent Sud Méditerranée I Ethics Committee on 12 June 2012 (EudraCT 2014-003666-25). The study was carried out in accordance with the Helsinki declaration and good clinical

practices guidelines, and patients signed a written informed consent to participation in the study.

### Study design

This was an open-label, multicentre, single-arm phase IIIb study conducted in 17 centres in France. The study consisted of a screening, a treatment, and a follow-up period. During the treatment period (W0–W48), patients received 300 mg of subcutaneous secukinumab (two injections of 150 mg) weekly until W4, and every 4 weeks thereafter. If at W16 the treatment was judged by the investigator to be beneficial for the patient, 4-weekly injections were continued up to W48, either at the investigation site when attending a visit (W24, W32, W40 and W48) or at home between visits (W20, W28, W36 and W44). Patients were followed up to W52.

### Study objectives

The primary objective was to investigate the response of moderate-to-severe plaque psoriasis to secukinumab at W16 as assessed independently by the dermatologist and by the patient using proSPI-s (professionally assessed current severity domain of SPI) and saSPI-s (patient self-assessed current severity domain of SPI), respectively.

Secondary objectives were as follows: (i) to evaluate the correlation between PASI and proSPI-s; (ii) to assess each domain of proSPI and saSPI and the DLQI over the full duration of the study; and (iii) to evaluate safety of secukinumab up to W52. Additional exploratory objectives were to evaluate the correlations between: (iv) saSPI-s and PASI; (v) proSPI-s and saSPI-s; and (vi) the psychosocial impact scores, SPI-p and DLQI.

### Efficacy and safety analyses

Efficacy parameters were analysed on the full analysis set (FAS) population, which comprised all patients from the included population who were administered at least one dose of investigational drug with at least one baseline and one post-baseline SPI evaluation.

Efficacy of secukinumab was assessed by examining absolute and percentage changes from baseline of PASI and of DLQI at W16 and at W52. The proSPI-s and saSPI-s scores at the same time points were compared with each other and with PASI. SPI-p was compared with DLQI.

Safety of secukinumab was evaluated by the summary of treatment-emergent adverse events (AEs) including severity, study treatment-related AEs, serious adverse events (SAEs), AEs leading to study drug discontinuation, and AEs leading to death.

### Statistical analysis

Continuous variables are presented as means ( $\pm$ standard deviation) and graphically as medians and interquartile ranges; categorical variables are presented as numbers of patients and percentages. Comparisons between the mean proSPI-s, saSPI-s

and PASI between baseline and W16 were tested by the paired t-test after confirmation that the data sets were normally distributed. Correlation between scales (proSPI-s vs. PASI; SPI-p vs. DLQI; proSPI-s vs. saSPI-s) at each post-baseline visit was estimated using Spearman's rank correlation coefficient. A  $p$ -value  $\leq 0.05$  was considered significant. Statistical analyses were performed using SAS version 9.4. (SAS Institute, Cary, NC, USA).

## Results

### Demographic and disease characteristics

Between 20 May 2015 and 06 Jan 2016, 137 patients were screened. Of them, 120 were entered into the study, 111 (92.5%) completed the initial 16-week induction treatment, and 100 (83.3%) continued treatment to W48.

Of the 120 patients (mean age  $\pm$  SD: 45.9  $\pm$  14.2 years), 111 (92.5%) were  $\leq 65$  years, 83 (69.2%) were male, and 116 (96.7%) were Caucasian. At the time of recruitment, patients had had psoriasis for a mean ( $\pm$ SD) of 21.  $\pm$  (12.8) years; psoriasis involving significant body sites was recorded in the following proportion of cases: scalp 47.5%, nails 33.3%, and palmoplantar skin 19.2%. Patient and disease characteristics at baseline are presented in Table S1 (Supporting Information). All but one subject (119/120) had previously received systemic psoriasis treatment (including retinoids, methotrexate or ciclosporin) and/or phototherapy; 63/120 (52.5%) were naïve to biologic psoriasis therapy.

### Primary efficacy endpoint

The FAS population comprised 119 patients. The mean ( $\pm$ SD) proSPI-s score in the FAS population decreased significantly from 24.9 ( $\pm 10.8$ ) at baseline to 2.3 ( $\pm 6.1$ ) at W16, which corresponded to an absolute change of 22.6 ( $P < 0.0001$ ) and a relative change of  $-90.9\%$  (Fig. 2). The mean ( $\pm$ SD) saSPI-s score at baseline was 23.5 ( $\pm 10.4$ ) and decreased to 2.0 ( $\pm 4.5$ ) by W16, which corresponded to a mean absolute change of  $-21.6$  ( $P < 0.0001$ ) and a relative change of  $-88.8\%$  (Fig. 2).

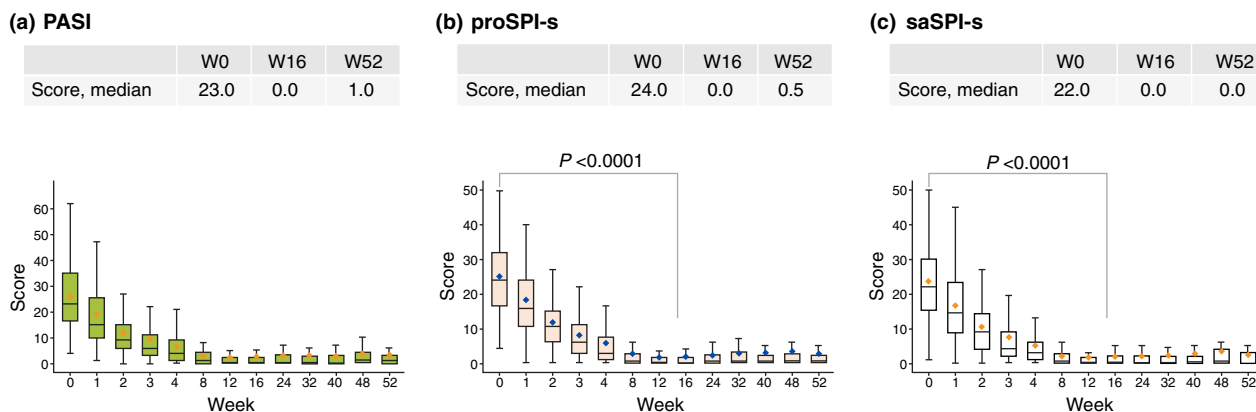
### Secondary endpoints

The mean ( $\pm$ SD) PASI score decreased from 23.0 ( $\pm 10.5$ ) at baseline to 2.2 ( $\pm 3.9$ ) at W16 ( $P < 0.0001$ ) and 3.2 ( $\pm 5.4$ ) at W52.

The correlation between proSPI-s and PASI was moderate at baseline (0.69) and strong from W2 (0.76) up to W52 (0.93). By W16, PASI-50 was achieved in 96.3% (105/109), PASI-75 in 85.3% (93/109), PASI-90 in 68.8% (75/109) and PASI-100 in 38.5% (42/109). At W52, PASI-50, PASI-75, PASI-90 and PASI-100 response rates were 93.5% (86/92), 83.7% (77/92), 65.2% (60/92) and 37.0% (34/92), respectively.

The decreases of mean proSPI-s and saSPI-s scores observed at W16 were maintained to W52 with absolute reductions of 22.2 (88.5%) and 21.8 (81.9%), respectively (Fig. 2).

Data from proSPI-s showed that psoriasis affecting functionally or psychosocially significant sites was extensive (extent



**Figure 2** Changes in mean and median psoriasis severity scores over the course of the study (full analysis set population,  $N = 119$ ): (a) Psoriasis Area and Severity Index (PASI), (b) professionally assessed Simplified Psoriasis Index (SPI) current severity score (proSPI-s) and (c) patient self-assessed SPI current severity score (saSPI-s). Means are represented by diamonds; medians with interquartile and overall ranges are represented by box and whisker plots.

score = 1) at baseline in the following proportions of patients: scalp and hairline 44.5%; face, neck and ears 23.5%; hands, fingers and fingernails 40.3%; feet, toes and toenails 43.7%; and anogenital area 34.5%. These proportions decreased markedly in all these sites by W16 (ranging from an 83.0% reduction in the numbers of patients with extensive involvement of ‘feet, toes and toenails’ to 97.4% and 100% reductions in those with extensive involvement of ‘anogenital area’ and ‘face, neck and ears’, respectively). These improvements were maintained to W52 (Fig. 3).

The mean ( $\pm$ SD) psychosocial impact scores (SPI-p: range 0–10) decreased over the course of the study from 8.2 ( $\pm$ 1.9) at baseline to 1.3 ( $\pm$ 2.2) at W16 and 1.5 ( $\pm$ 2.1) at W52 (Fig. 4). The mean ( $\pm$ SD) DLQI score at baseline was 13.6 ( $\pm$ 7.4). By W16, the score had decreased by 83.5% to reach ‘moderate impact’ levels [mean ( $\pm$ SD): 2.1 ( $\pm$ 3.67)], a change sustained until W52 [mean ( $\pm$ SD): 1.9 ( $\pm$ 3.4); Fig. 4]. The percentage of patients with DLQI status of 0/1 (i.e. psoriasis was considered as having no effect at all on the patient’s life) increased from 3.4% at baseline to 67.9% at W16 and to 68.9% at W52.

The correlation between saSPI-s and PASI was weak at baseline (0.49) but moderate (0.65) at W52. The Spearman correlation coefficients between proSPI-s and saSPI-s are shown in Table 1. The correlation between the psychosocial impact scores, SPI-p and DLQI, increased from 0.55 at baseline to 0.84 at W52.

**Safety**

The safety population comprised 120 patients. At least one adverse event was recorded in 110 (91.7%) patients, of which 65 (54.2%) were considered by the supervising physician to be related to the study treatment. The most frequent adverse event was nasopharyngitis (10.8%). At least one serious adverse event

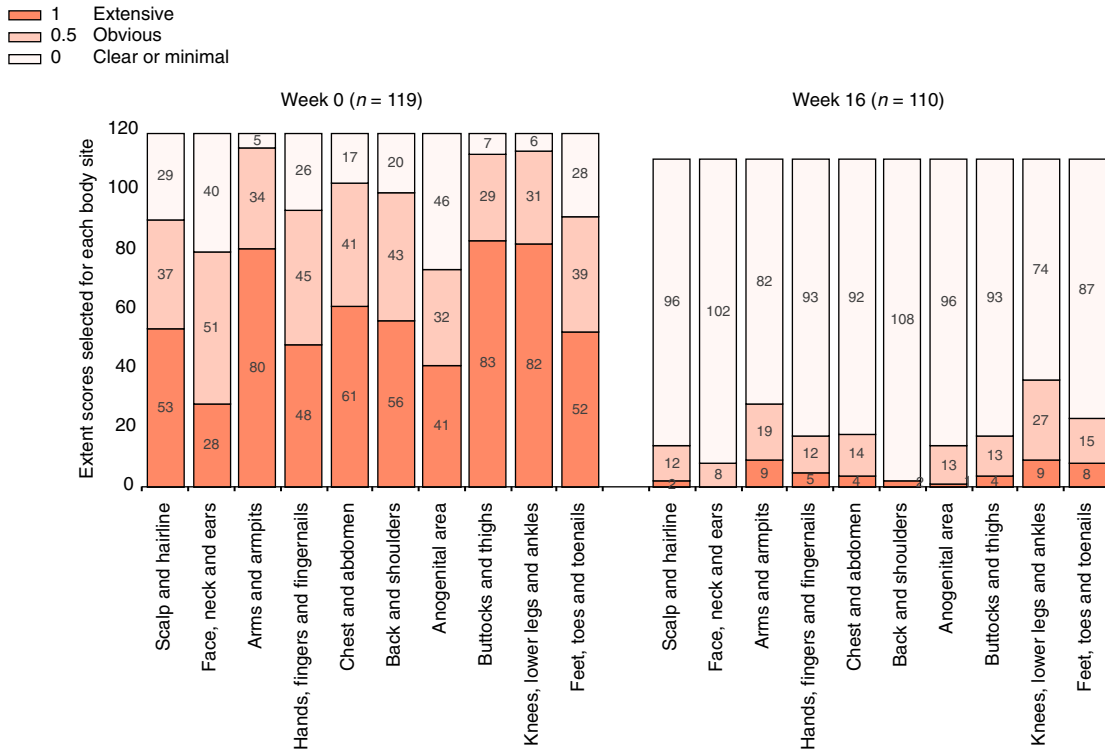
was documented in 13 (10.8%) patients, of which two (1.7%) experienced events that were considered by the supervising physician to be due to the study drug (stomatitis in one patient and punctate keratitis and Sjögren syndrome in the other). Five patients had an adverse event that led to discontinuation of secukinumab. Two patients died during the study but the causes of death (cranial trauma and cutaneous lymphoma) were not related to the study treatment.

**Discussion**

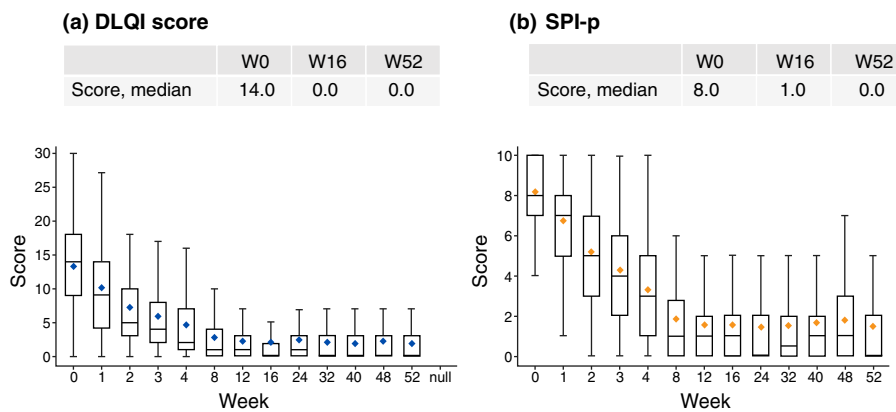
We present here the results from a clinical study designed to assess the utility of SPI for documenting response to secukinumab treatment in patients with moderate-to-severe plaque psoriasis using a validated translation of SPI into French.

The study has shown that the current severity domain of both versions of SPI (proSPI-s and saSPI-s) successfully demonstrated their ability to capture the progressive fall in psoriasis extent and severity in response to the introduction of secukinumab in patients with moderate-to-severe psoriasis. Major reductions in mean proSPI-s and saSPI-s scores were already apparent by W8 (Fig. 2) and reached 90.9% and 88.8%, respectively, at W16. These improvements were then maintained throughout the remainder of the study.

The study has demonstrated that the ability of proSPI-s to capture response to therapy is comparable to that achieved by PASI, with a strong correlation between the two instruments over time. This confirms that SPI is at least as reliable an instrument as PASI for assessing psoriasis severity. Furthermore, the fact that saSPI-s (patient self-assessed severity) is strongly correlated with proSPI-s (physician-assessed severity) indicates that patients and physicians have similar perceptions of psoriasis severity. This is an important point for managing patients in



**Figure 3** proSPI-s scores at Week 0 and Week 16 for each of 10 body sites. Numbers of scores for each extent category: (1) widespread and involving much of the affected area; (0.5) obvious but still leaving plenty of normal skin and (0) clear or minimal with no more than a few scattered thin plaques.



**Figure 4** Changes in mean and median psychosocial impact scores over the course of the study (full analysis set population,  $N = 119$ ): (a) Dermatology Life Quality Index (DLQI) and (b) Simplified Psoriasis Index psychosocial impact score (SPI-p). Means are represented by diamonds; medians with interquartile, and overall ranges are represented by box and whisker plots.

**Table 1** (a) Correlation analyses between PASI, proSPI-s and saSPI-s. (b) Correlation analyses between (i) psoriasis severity scores (PASI, proSPI-s and saSPI-s) and psychosocial impact scores (SPI-p and DLQI); and (ii) the two psychosocial impact scores

(a)						
	Spearman's correlation coefficient (95% CI)					
	PASI			saSPI-s		
	Baseline	W16	W52	Baseline	W16	W52
proSPI-s	0.691 (0.58, 0.78)	0.814 (0.74, 0.87)	0.927 (0.89, 0.95)	0.551 (0.41, 0.67)	0.677 (0.56, 0.77)	0.715 (0.60, 0.80)
saSPI-s	0.490 (0.34, 0.62)	0.701 (0.59, 0.79)	0.645 (0.51, 0.75)			

(b)						
	Spearman's correlation coefficient (95% CI)					
	SPI-p			DLQI		
	Baseline	W16	W52	Baseline	W16	W52
PASI	0.173 (-0.01, 0.34)	0.678 (0.56, 0.77)	0.749 (0.64, 0.83)	0.497 (0.34, 0.62)	0.585 (0.43, 0.71)	0.694 (0.54, 0.82)
proSPI-s				0.224 (0.04, 0.39)	0.418 (0.250, 0.56)	0.514 (0.34, 0.65)
saSPI-s				0.480 (0.33, 0.61)	0.666 (0.55, 0.76)	0.716 (0.60, 0.80)
SPI-p				0.551 (0.41, 0.67)	0.774 (0.69, 0.84)	0.840 (0.77, 0.89)

CI, confidence interval; DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index; proSPI-s, professionally assessed psoriasis severity score; saSPI-s, patient self-assessed psoriasis severity score; SPI-p, patient psychosocial impact score; W, week.

routine clinical practice where the SPI can be completed by the patient, saving the physician time and giving the patient some measure of ownership of their disease management.

The limitations of PASI for scoring psoriasis are well known. SPI has been designed to capture the additional functional and psychological impact of psoriasis involving certain body sites, which are also often difficult to treat: the scalp, face, hands and feet (including nails) and anogenital area account for up to 50% of the SPI extent score.<sup>15,16</sup> SPI has the advantage over PASI of enabling response to treatment in each of its ten body sites to be assessed independently. The efficacy of secukinumab could be demonstrated by SPI-s in each of these sites, thus providing a more sophisticated assessment of treatment response than is possible with PASI. By way of example, scalp psoriasis was extensive (extent score = 1) in 44.5% of patients at baseline and in only 1.8% at W16, an improvement which was sustained to W52. Similar responses to secukinumab were observed for the anogenital, hands and feet locations, supporting previous secukinumab studies dedicated to specific psoriasis locations in which site-specific questionnaires were used (GESTURE NCT01806597, TRANSFIGURE NCT01807520 and SCALP NCT02267135).<sup>17–19</sup>

Based on the mean DLQI value at baseline, psoriasis had a very strong impact on patients' quality of life (QoL). As observed in previous phase III studies, there was a marked decrease in mean DLQI scores in response to secukinumab, from 13.6 at baseline to 2.1 at W16 (83.5% reduction) and 1.9 at W52.<sup>2,20,21</sup> These changes were paralleled by reductions in patients' SPI psychosocial impact scores (SPI-p), which decreased from 8.2 at baseline to 1.3 at W16 (84.1% reduction) and 1.5 at W52. These similar responses were reflected in the

strong correlation between SPI-p and DLQI over time. It should be noted, however, that the full range of SPI-p scores (0–10) was used whereas the top half of the range of DLQI (16–30) was little used.

Incorporation of a psychosocial impact assessment into an instrument for assessing psoriasis severity enhances its utility as a score for global assessment of the disease not only for clinical studies but also for daily clinical practice. An additional advantage of SPI lies in its ability to capture the burden and responsiveness of psoriasis affecting functionally or psychosocially important body sites that may disproportionately affect a patient's QoL. The ability of patients to record the severity and impact of their psoriasis themselves using saSPI not only gives them some ownership of the management of their disease but also provides a means for physicians to be able to monitor response to treatment remotely.

The safety profile of secukinumab was consistent with that previously reported,<sup>2,20,21</sup> and no new or unexpected signals were identified during the study. Discontinuation of therapy due to an adverse event occurred in 4.2% of patients. There were two deaths during the study that were deemed unrelated to study treatment.

## Conclusions

The French version of SPI, the relevant domains of which (SPI-s and SPI-p) correlated well with PASI and DLQI, respectively, appears to provide a simple mean of assessing psoriasis severity, its psychosocial impact and the response of both to treatment. Furthermore, SPI enables the anatomical distribution of psoriasis and the differential responses to intervention in different body sites to be documented more clearly. SPI was found by

dermatologists and patients alike to be straightforward to use and thus suitable for use both in clinical trials and in routine clinical practice.

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### Supporting information

Additional Supporting Information may be found in the online version of this article:

**Figure S1.** French version of proSPI.

**Figure S2.** French version of saSPI.

**Table S1.** Baseline demographic and disease characteristics of included patients.