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## ORIGINAL

# Demographic characteristics and health-related quality of life of patients with moderate-to-severe psoriasis: The VACAP study

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Received 9 August 2012; accepted 9 March 2013

Available online 1 July 2013

## KEYWORDS

Psoriasis;  
Quality of life;  
Short-Form 36;  
EuroQol-5D;  
Dermatology Life  
Quality Index;  
Psoriasis Disability  
Index

## Abstract

**Background:** Psoriasis is associated with a deterioration in the health-related quality of life (HRQoL) of affected patients. The aim of this study was to assess the HRQoL of patients with moderate-to-severe psoriasis.

**Methods:** A prospective observational study (the VACAP Study) was carried out in 123 centers in Spain with 1217 patients. Patients were evaluated at baseline (visit 1 [V1]) and again four months later (visit 2 [V2]). The severity of psoriasis was determined using the following indices: (i) Psoriasis Area and Severity Index (PASI) (score range 0–72, higher score indicates more severe disease), (ii) the body surface area (BSA) affected, and (iii) the Physicians Global Assessment (PGA) (range 1–7, higher score indicates more severe disease). Four questionnaires were used for the assessment of the HRQoL: (i) the Short-Form 36 quality-of-life questionnaire (SF-36) (score range 0–100, higher score indicates better HRQoL); (ii) Euroqol (EQ-5D) (range from 1 to 3, lower score indicates better HRQoL); (iii) Dermatology Life Quality Index (DLQI) (ranges 0–30; from best to worst HRQoL); and (iv) Psoriasis Disability Index (PDI) (ranges 0–45; higher score indicates better HRQoL).

**Results:** The mean (SD) age of the patients was 45.11 (13.92) years at V1. The mean age at the onset of psoriasis was 26.08 (14.19) years. The majority of patients were female (61%) and were employed (68%). The mean PASI score was 13.24 (9.50) at V1 and 5.07 (6.03) at

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**PALABRAS CLAVE**

Psoriasis;  
Calidad de vida;  
Short-Form 36;  
EuroQol-5D;  
Índice de Calidad de  
Vida en  
Dermatología;  
Índice de  
Discapacidad de la  
Psoriasis

V2 ( $P < .001$ ). Scores from the generic HRQoL questionnaires (EQ-5D, SF-36) showed significant improvement between visits in all dimensions measured ( $P < .001$ ). The disease-specific questionnaires also revealed overall improvements in quality of life over time: the DLQI mean total score was 8.97 (7.28) at V1 and 4.76 (5.72) at V2 ( $P < .001$ ), and the PDI mean total score was 9.24 (8.76) V1 and 4.88 (6.65) at V2 ( $P < .001$ ). Multivariate analysis using PDI as the dependent variable showed that the principal factors related to HRQoL were severity of psoriasis as measured by PASI ( $P < .001$ ), and gender ( $P = .048$ ).

**Conclusions:** The principal factor related to HRQoL in patients with psoriasis is the severity of the disease.

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### Características demográficas y calidad de vida relacionada con la salud en pacientes con psoriasis moderada a grave: Estudio vacap

#### Resumen

**Antecedentes:** La psoriasis se asocia a un deterioro de la Calidad de Vida Relacionada con la Salud (CVRS) de los pacientes. El objetivo de este estudio fue valorar la CVRS en pacientes con psoriasis moderada a grave.

**Métodos:** Se llevó a cabo un estudio prospectivo observacional (Estudio VACAP) sobre 1217 pacientes distribuidos en 123 centros de España. Los pacientes fueron evaluados al inicio del estudio (visita 1 [V1]) y de nuevo 4 meses más tarde (visita 2 [V2]). Para determinar la gravedad de la psoriasis se emplearon los siguientes índices: a) el índice de gravedad y de área de la psoriasis (Psoriasis Area and Severity Index [PASI]) (valores entre 0-72, las puntuaciones más altas indican una mayor gravedad de la enfermedad); b) el índice de superficie corporal afectada (Body Surface Area [BSA]), y c) la evaluación general efectuada por el médico (Physicians Global Assessment [PGA]) (intervalo entre 1-7: los valores más altos son indicativos de una enfermedad más grave). Para evaluar la CVRS se utilizaron 4 tipos de cuestionarios: a) el Cuestionario de Calidad de Vida SF-36 (SF-36) (escala de puntuación entre 0-100, los valores más altos indican una mejor CVRS); b) el EuroQol (EQ-5D) (intervalo comprendido entre 1-3, cuanto más bajos sean los resultados obtenidos mejor es la CVRS); c) el Índice de Calidad de Vida en Dermatología (Dermatology Life Quality Index [DLQI]) (intervalo entre 0-30; de mejor a peor CVRS); y d) el Índice de Discapacidad de la Psoriasis (Psoriasis Disability Index [PDI]) (escala de puntuación entre 0-45, los datos más altos muestran una mejor CVRS).

**Resultados:** La edad media de los pacientes (desviación estándar [DS]) en la V1 fue de 45,11 (13,92) años. La edad media de inicio de la psoriasis fue de 26,08 (14,19) años. La mayoría de los pacientes eran mujeres (61%) y trabajadoras (68%). El valor medio del PASI fue de 13,24 (9,59) en la V1 y de 5,07 (6,03) en la V2 ( $p < 0,001$ ). Las puntuaciones de los cuestionarios de CVRS genéricos (EQ-5D, SF-36) mejoraron significativamente en todas las dimensiones evaluadas entre las 2 visitas ( $p < 0,001$ ). Los cuestionarios específicos de enfermedad también revelaron la mejoría general de la calidad de vida a lo largo del tiempo: la puntuación media total del DLQI fue de 8,97 (7,28) en la V1 y de 4,76 (5,72) en la V2 ( $p < 0,001$ ), y los valores medios totales del PDI fueron de 9,24 (8,76) en la V1 y 4,88 (6,65) en la V2 ( $p < 0,001$ ). El análisis multivariado, siendo el PDI la variable dependiente, mostró que los principales factores relacionados con la CVRS eran la gravedad de la psoriasis, medida por PASI, ( $p < 0,001$ ) y el sexo ( $p = 0,048$ ).

**Conclusiones:** El principal factor relacionado con la CVRS en pacientes con psoriasis es la gravedad de la enfermedad.

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## Introduction

The prevalence of psoriasis varies between 0% and 11.8%.<sup>1,2</sup> The difference in these estimates reflects, to a large extent, the different methods used to obtain the data. For example, the prevalence reported in population-based studies is between 0.2% and 4.8%. The variability of environmental and genetic factors in different countries also has a significant effect on prevalence. The average prevalence in Europe is around 2% and, in Spain, it has been estimated to be 1.4%.<sup>3</sup>

The impairment in the health-related quality of life (HRQoL) in psoriasis patients is well documented<sup>4-7</sup> and may be more marked than in other chronic diseases.<sup>8-11</sup> To determine the HRQoL of a psoriasis patient, it is important to determine which aspects of the patient's life are impaired. The generic HRQoL questionnaires are suitable for this purpose. One of the most commonly used generic instruments is the Short-Form 36 (SF-36) quality-of-life questionnaire.<sup>12-16</sup> The EuroQol questionnaire (EQ-5D) is also widely used because of its simplicity of administration and good psychometric properties.<sup>17-19</sup> Questionnaires that focus on specific

pathologies can also be particularly useful. For example, the Dermatologic Life Quality Index (DLQI)<sup>20-22</sup> is a valuable tool for assessing quality of life in patients with dermatological disorders, while the Psoriasis Disability Index (PDI)<sup>23-25</sup> assesses the effects of specific aspects of the disease on patients. These questionnaires evaluate the impact of the disease on the lives of patients with psoriasis and highlight aspects of daily life that are significantly affected by the disease. The results of these questionnaires are critical for the clinical management of psoriasis.

The objective of the present study was to describe the demographic and clinical characteristics of patients with moderate-to-severe psoriasis and to assess the impact of psoriasis and its treatment on patients' quality of life.

## Methods

### Study design

This was a multicenter prospective observational study carried out in 123 centers throughout Spain (the Evaluation of the Health-Related Quality of Life and Use of Resources in Patients with Moderate-to-Severe Plaque Psoriasis in Spain [VACAP] Study). The study was approved by the ethics committee of Hospital La Princesa in Madrid, Spain. Patients were recruited consecutively at each of the participating centers. The recruitment period was from August 9, 2007, to December 21, 2007, and written informed consent was obtained from all patients prior to their participation in the study. All patients were seen at 2 visits. Demographic data and clinical characteristics, including disease severity and HRQoL variables, were gathered at the first visit, and disease severity and HRQoL were re-evaluated at the 4-month follow-up visit.

### Patients

A total of 1217 patients were recruited. The inclusion criteria were age 18 years or older and a diagnosis of moderate-to-severe psoriasis. Patients with psoriatic arthritis and those participating in other clinical trials were excluded. For the purpose of this study, 4 criteria were established for the diagnosis of moderate-to-severe psoriasis: (a) a Psoriasis Area and Severity Index (PASI) score equal to or greater than 10, (b) a Physician Global Assessment (PGA) score of 5 or higher, (c) affected body surface area (BSA) greater than 10%, and (d) any clinical indication for systemic treatment.

### Assessment of demographic and clinical characteristics of patients with psoriasis

The following demographic data were recorded: age, weight, educational level, employment status, and smoking history. Psoriasis severity was assessed using 3 different tools: PASI,<sup>2,8</sup> PGA, and affected BSA. The PASI evaluates the severity of the psoriasis and the surface area affected.

## HRQoL assessment

HRQoL assessment was carried out using 4 different questionnaires: the Dermatology Quality of Life Index (DLQI),<sup>20-22</sup> the Psoriasis Disability Index (PDI),<sup>23-25</sup> the EuroQol questionnaire (EQ-5D),<sup>17-19</sup> and the Short-Form 36 (SF-36).<sup>12-16</sup>

The DLQI evaluates the impact of dermatological illnesses and their treatment on the well-being of affected patients. It consists of 10 items organized into 6 dimensions: symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment. Each item has 4 response options scored from 0 to 3, giving a maximum score of 30. Higher scores indicate a poorer HRQoL.

The PDI questionnaire is composed of 15 items that assess daily activities, work or school, personal relationships, leisure, and the effects of psoriasis treatment; the items refer only to the month prior to administration of the questionnaire. Items are scored from 0 to 3, with a maximum score of 45. Higher scores correspond to a poorer quality of life.

The Short-Form 36 (SF-36) is composed of 36 items that represent 8 different HRQoL dimensions. Two summary scores are obtained: a physical component summary and a mental component summary. The scores range from 0 to 100, with higher scores indicating better health.

The EQ-5D is an instrument designed to measure general health status. It consists of 5 items rated on a 3-point scale with possible responses ranging from "No Problem" to "Extreme Problem" or "Unable to do." The questionnaire includes a visual analogue scale (a printed picture of a thermometer) on which patients indicate their evaluation of their overall HRQoL. This visual analogue scale is scored from 0 (worst HRQoL) to 100 (best HRQoL).

## Statistical analysis

A database was constructed with the information obtained from the first and second visits. Quantitative data from the questionnaires and scales were analyzed to determine the mean, variance, standard deviation, minimum, maximum, median, 95% confidence interval, and 5% trimmed mean. For categorical data, the responses were calculated. Means were compared using the *t* test or nonparametric Mann-Whitney *U* test, and comparisons of frequency distributions were performed with the Pearson  $\chi^2$  test or Fisher exact test when a  $2 \times 2$  contingency table was applicable. The level of statistical significance was set at  $\alpha = 0.05$ . Lineal regression analysis was used to evaluate the relationship between demographic and clinical characteristics and the HRQoL. The dependent variable was the difference in the PDI between the first and second visits. Independent variables were included in a stepwise, algorithmic manner in the model, with a probability to enter of 0.05 and a probability to leave of 0.10. Categorical variables were transformed into dummy variables. Missing values were excluded from the analyses.

All statistical analyses were performed with the Predictive Analytics Software version 18.0 (PASW Statistics® 18.0).

**Table 1** Demographic data.

Variable	Value
Age, y mean (SD)	45.11 (13.92)
<i>Age distribution</i>	%
18–30	15.5
31–40	26.0
41–50	24.2
51–60	18.9
>60	15.5
<i>Gender</i>	%
Male	60.8
Female	39.2
Weight, kg mean (SD)	76.82 (15.92)
<i>Smoking status</i>	%
Nonsmokers	40.0
Smokers	36.6
Ex-smokers	23.4
<i>Educational level</i>	%
No formal education	4.1
Primary education	39.8
Secondary education	34.1
University education	22.0
<i>Work status</i>	%
Employed	68.1
Unemployed	6.5
Housewife	10.2
Retired	13.7
Retired due to the psoriasis	1.5

## Results

### Demographic and clinical characteristics

The mean (SD) age of the patients was 45.1 (13.9) years (15.3% were over 60 years) and 60.8% were men. The mean age of the patients at disease onset was 26.08 (14.19) years, and 76.7% were between 18 and 40 years of age at the time of disease onset. At the time of the study, 68.1% of patients were working and 15.2% were retired (1.5% had retired because of their psoriasis). The demographic characteristics are shown in [Table 1](#).

Based on the assessment of a dermatologist at the first visit, 60.8% of patients were considered to have moderate psoriasis and 39.2% to have severe psoriasis. The mean weight of the patients was 76.8 (15.9) kg, 36.2% were smokers, and 49.6% had relatives with psoriasis, of whom 65.4% were first-degree relatives. The mean number of exacerbations of psoriasis in the previous year was 2.4 (1.9), and 10.5% of patients had chronic rash. The most commonly affected areas were the trunk and upper limbs (83.8% and 90.4%, respectively). In 46.3% of patients there were most comorbid conditions associated with the psoriasis, the most frequent of which were metabolic diseases (32.7%), neurological and mental disorders (32.0%), cardiovascular diseases (28.1%), and autoimmune diseases (20.8%). The clinical data of patients participating in the study are summarized in [Table 2](#).

**Table 2** Clinical data.

Variable	Value
Age at onset of psoriasis mean (SD)	26.08 (14.19)
<i>Age range at onset of psoriasis</i>	%
18–30	55.2
31–40	21.5
41–50	13.5
51–60	7.0
>61	2.8
No. of exacerbations in the previous year mean (SD)	2.42 (1.94)
<i>No. of exacerbations per patient</i>	%
None	4.3
1–2	54.4
3–4	22.9
>4	7.9
Chronic	10.5
<i>Relatives with psoriasis</i>	%
Overall study population	50.4
First-degree relatives	65.4
Second-degree relatives	34.6
Patients on treatment between 1 <sup>st</sup> and 2 <sup>nd</sup> visit, %	80.1
<i>Treatments between 1<sup>st</sup> and 2<sup>nd</sup> visit</i>	%
Topical	53.6
Biological	36.1
Systemic	27.6
Phototherapy	14.1
Others	17.5
Patients with comorbidities, %	46.3
<i>Comorbidities</i>	%
Immune disease	20.8
Cancer	6.4
Cardiovascular disease	28.1
Dermatological disease	2.5
Infectious disease	12.4
Hematological disease	2.7
Metabolic disease	32.7
Mental and neurological disease	32.0
Rheumatic and joint disease	4.4
Renal impairment	3.7
Respiratory disease	7.6
Others	8.2
<i>Area affected by psoriasis</i>	%
Whole body	4.8
Head and neck	59.8
Trunk	83.8
Upper extremities	90.4
Lower extremities	45.9

### Severity of psoriasis

The mean PASI score at the first visit was 13.24 (9.50), and this fell to 5.07 (6.03) at the second visit. In all, 730 patients (60.0%) achieved PASI50 on their second visit, and 500 patients (41.1%) achieved PASI75. The mean PGA score decreased from 4.93 (1.32) at baseline to 3.27 (1.53) at the second visit. On the basis of the BSA criteria for assessing the severity of psoriasis, 89.2% of patients were in the

**Table 3** Results of the indices and questionnaires.<sup>a</sup>

	First visit	Second visit	P value
PASI	13.24 (9.50)	5.07 (6.03)	<.001
PGA	4.93 (1.33)	3.27 (1.53)	<.001
<i>BSA, %</i>			
Mild	10.8	48.2	<.001
Moderate	41.1	37.2	
Severe	47.6	14.6	
<i>Short-Form 36</i>			
Physical functioning	83.67 (21.44)	86.79 (19.53)	<.001
Role-physical	78.02 (25.97)	83.58 (22.48)	<.001
Bodily pain	67.08 (29.35)	73.56 (27.96)	<.001
General health	56.25 (21.46)	59.19 (21.05)	<.001
Vitality	58.95 (21.34)	62.70 (20.34)	<.001
Social functioning	76.14 (25.82)	83.80 (22.09)	<.001
Role emotional	81.33 (23.63)	86.47 (20.26)	<.001
Mental health	65.00 (21.72)	68.60 (19.96)	<.001
Physical component summary	49.43 (8.83)	50.81 (8.34)	<.001
Mental component summary	45.35 (11.96)	48.07 (10.33)	<.001
<i>EQ-5D</i>			
Mobility	1.21 (0.42)	1.15 (0.36)	<.001
Self-care	1.11 (0.33)	1.07 (0.26)	<.001
Usual activities	1.29 (0.47)	1.20 (0.43)	<.001
Pain/discomfort	1.57 (0.58)	1.42 (0.56)	<.001
Anxiety/depression	1.48 (0.60)	1.35 (0.55)	<.001
Visual analogue scale	64.41 (18.00)	72.44 (17.88)	<.001
<i>DLQI</i>			
Global Score	8.97 (7.28)	4.76 (5.72)	<.001
Symptoms and feelings	2.74 (1.81)	1.60 (1.59)	<.001
Daily activities	1.75 (1.74)	0.91 (1.35)	<.001
Leisure	1.58 (1.79)	0.80 (1.33)	<.001
Work/school	0.78 (1.01)	0.36 (0.73)	<.001
Personal relationships	1.15 (1.62)	0.57 (1.14)	<.001
Treatment	1.03 (1.01)	0.55 (0.81)	<.001
<i>PDI</i>			
Total score	9.24 (8.76)	4.88 (6.66)	<.001
Daily activities	4.43 (3.77)	2.39 (3.02)	<.001
Work/school	1.39 (2.04)	0.69 (1.45)	<.001
Personal relationships	0.97 (1.42)	0.50 (1.03)	<.001
Leisure	1.96 (2.46)	1.03 (1.76)	<.001
Treatment	0.53 (0.77)	0.29 (0.57)	<.001

<sup>a</sup> Data presented as mean (SD) except for BSA presented as percentage.

moderate-to-severe psoriasis range at the first visit, and this fell to 51.8% at the second visit. These results are summarized in [Table 3](#).

During the previous year, 95.6% of the patients had received treatment for psoriasis; 35.7% had received biological therapies.

### Health-related quality of life

The SF-36 dimensions with the best mean scores at the first visit were physical functioning (83.67 [21.44]), followed by role-emotional (81.33 [23.63]), and role-physical (78.02 [25.97]). The dimensions that showed the greatest

improvement between visits were social functioning (increase from 76.14 [25.82] to 83.80 [22.09]), role-physical (increase from 78.02 [25.97] to 83.58 [22.48]), and bodily pain (increase from 67.08 [29.35] to 73.56 [27.96]). These changes were statistically significant ( $P < .001$ ).

The EQ-5D dimensions with the lowest scores at the first visit were pain (1.57 [0.58]) and anxiety/depression (1.42 [0.56]). The dimensions that showed the greatest improvement at the second visit were pain (1.48 [0.60]) and anxiety/depression (1.35 [0.55]).

The DLQI score fell from 8.97 (7.28) at baseline to 4.76 (5.72) at the second visit. This improvement was reflected in all dimensions, and all the changes were statistically significant ( $P < .001$ ). The changes in the PDI score were also

**Table 4** Multivariate linear regression analysis.

Model summary	$R^2$	Adjusted $R^2$	$P$ value
PDI <sup>a</sup> = PASI <sup>b</sup> + Gender <sup>c</sup>	0.168	0.165	<.001
Variables summary	Beta (standardized coefficients)		$P$ value
PASI <sup>b</sup>	0.405		<.001
Gender <sup>c</sup>	0.075		.048

<sup>a</sup> PDI: PDI second visit – PDI first visit.

<sup>b</sup> PASI: PASI second visit – PASI first visit.

<sup>c</sup> Gender coded as 0: female and 1: male.

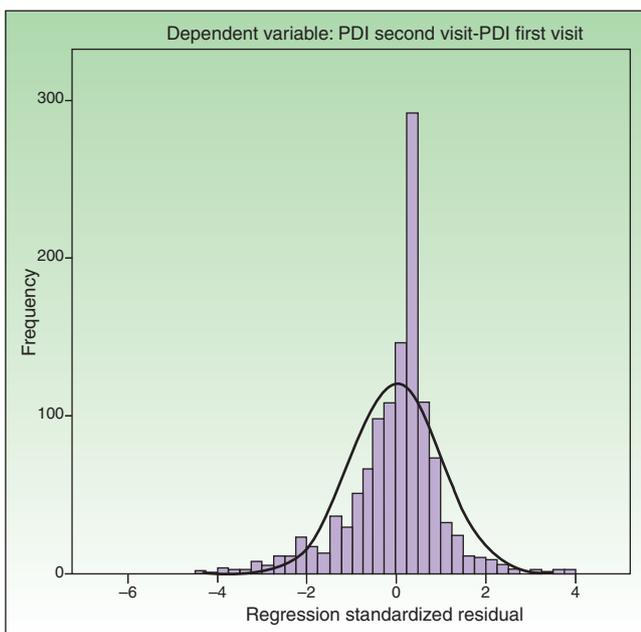
statistically significant, with a fall from 9.24 (8.76) at baseline to 4.88 (6.66) at the second visit ( $P < .001$ ). The results of the HRQoL questionnaires are summarized in Table 3.

The results of the multivariate analysis reveal that disease severity and extent (measured by the PASI score) ( $b = 0.405$ ;  $P < .001$ ) and gender ( $b = 0.075$ ;  $P = .048$ ) were the most significant factors in determining a patient's quality of life. A summary of the results of the multivariate linear regression is shown in Table 4. The residual plots are shown in Figs. 1 and 2. These plots show that the linear model provides a suitable fit to the data.

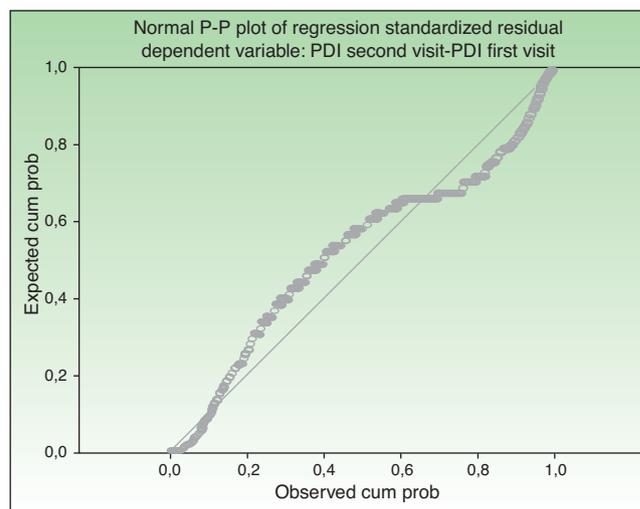
## Discussion

### Demographic and clinical profile

The demographic characteristics of the patients in the VACAP study are similar to those reported in other studies on psoriasis patients. The mean age at disease onset was also similar to the age reported in other studies from Spain.<sup>3,5,26,27</sup> According to the results obtained in



**Figure 1** Standardized residual histogram<sup>a</sup>. (<sup>a</sup>Psoriasis Disability Index scores: visit 2 – visit 1).



**Figure 2** Normal probability–probability plot of regression standardized residuals. <sup>a</sup>Psoriasis Disability Index scores: visit 2 – visit 1.

several European countries, psoriasis is most likely to appear between 15 and 30 years of age,<sup>4</sup> a finding supported by the results of our study, in which disease onset occurred in this age range in 55.2% of the patients.

Hensler et al.<sup>28</sup> proposed that there are 2 different types of psoriasis before 40 years, based on the age of onset: type I develops before 40 years and type II in patients older than 40 years. Those authors observed that type I psoriasis was associated with HLA-Cw6 and a positive family history of the disease. However, in the current study, only 23.3% of the patients were over 40 years of age at the time of disease onset, and the distribution did not follow the proposed bimodal pattern. We were thus unable to confirm Hensler et al.'s hypothesis.

Several studies report the importance of genetics in the onset of psoriasis.<sup>29–33</sup> In the current study, half of the patients stated that they had relatives with psoriasis and, of these, 65.4% were first-degree relatives. This is similar to the findings of other studies<sup>5,26</sup> and confirms the importance of genetic factors in an individual's susceptibility to psoriasis.<sup>2</sup>

### Psoriasis treatment effect

The percentage of patients treated with biological therapies was higher than has been observed in other studies, which have reported the use of biologics in approximately 5% of their overall study populations.<sup>4,5</sup> In the VACAP study, the prevalence of biological therapies was much higher, at around 36%. These results are a reflection of the major advances that have taken place in the treatment of psoriasis—these therapies, which are indicated for the treatment of patients with moderate-to-severe psoriasis, are associated with a reduction in disease severity and an improvement in the HRQoL.

## Impact of psoriasis on quality of life

Assessment by generic HRQoL questionnaires (SF-36, EQ-5D) shows the dimensions most affected in psoriasis patients to be those related to pain and psychological disturbances. Pain is the most common complaint, followed by itching.<sup>7</sup> The results of this study confirm that psoriasis impairs the mental health of affected patients.<sup>9,34–36</sup> Scores in the disease-specific HRQoL questionnaires (DLQI, PDI) had improved by the second visit, although these scores were already relatively low at baseline. A similar change was detected during the PDI validation study in Spain.<sup>25</sup> Those authors observed that their patients had low PDI scores, and highlighted potential, culturally specific issues with the administration of the PDI questionnaire to a Spanish population. In our study, the DLQI also yielded a low mean score at baseline. Ferrandiz et al.<sup>27</sup> proposed the need for a new HRQoL questionnaire to improve the sensitivity of quality-of-life assessments in patients with psoriasis. Despite these limitations, the results of the disease-specific questionnaires showed that psoriasis had a significant effect on quality of life, and multivariate analysis confirmed that there was a directly proportional linear relationship between the severity of psoriasis and the degree of impairment of the HRQoL. Patients with severe psoriasis had psychological distress,<sup>37,38</sup> a negative body self-image,<sup>39</sup> feelings of stigmatization,<sup>40</sup> and poorer social interactions<sup>39</sup>; these factors explained the impairment in the HRQoL.

Independently of the severity of psoriasis, HRQoL was poorer in women than in men. This gender-specific effect has not only been reported in previous publications on psoriasis<sup>38,40</sup> but has also been observed in other dermatological diseases such as hand eczema.<sup>41</sup> Finzo et al.<sup>38</sup> reported that a possible reason for this effect could be that women usually tend report more psychological disturbances than men. The VACAP study confirmed the main findings of other studies, specifically, that psoriasis leads to an impairment in the health-related quality of life. Our results show that a significant improvement in the severity index of the disease is related to an improvement in the health-related quality of life of affected patients.

## Ethical disclosures

**Protection of human and animal subjects.** The authors declare that the procedures followed were in accordance with the regulations of the responsible Ethics Committee and in accordance with those of the World Medical Association and the Helsinki Declaration.

**Confidentiality of data.** The authors declare that they have followed the protocols of their work centre on the publication of patient data and that no private patient data are disclosed in this article.

**Right to privacy and informed consent.** All the patients included in the study have received sufficient information and have given their informed consent in writing to participate in that study. The author for correspondence is in possession of this documentation.

## Conflicts of interest

This study received an unconditional grant from Schering-Plough. The funding institution exerted no control over the authors in terms of study design, analysis and interpretation of the data, elaboration of the report, and submission for publication.

## Acknowledgements

The authors thank Covadonga Torres of Pharmacoeconomics and Outcomes Research Iberia (PORIB) for her assistance with the statistical analysis and writing of the manuscript.

## Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <http://dx.doi.org/10.1016/j.ad.2013.03.005>.

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