

## INVESTIGATIVE REPORT

# Validation of a Specific Health-related Quality of Life Instrument in a Large Cohort of Patients with Psoriasis: The QualiPso Questionnaire

Bruno QUINTARD<sup>1</sup>, Aymery CONSTANT<sup>1</sup>, Marie-Laure BOUYSSOU-GAUTHIER<sup>2</sup>, Carle PAUL<sup>3</sup>, François TRUCHETET<sup>4</sup>, Pierre THOMAS<sup>5</sup>, Yves GUIGUEN<sup>6</sup> and Alain TAIEB<sup>7</sup>

<sup>1</sup>Laboratoire EA 4139 "Psychologie, Santé et Qualité de Vie", Université Victor Segalen Bordeaux 2., <sup>2</sup>Hôpital de Libourne, Libourne, <sup>3</sup>Paul Sabatier University and Dermatology Department, Toulouse, <sup>4</sup>Hôpital Bon Secours, Metz-Thionville, <sup>5</sup>Hôpital Huriez, Lille, <sup>6</sup>HIA Robert Piqué, Bordeaux, and <sup>7</sup>Hôpital Saint André, CHU de Bordeaux, Bordeaux, France

**The aim of this study was to develop and validate a standardized tool designed to assess health-related quality of life (HRQoL) in a large cohort of French patients with psoriasis, the QualiPso Questionnaire. A draft questionnaire was developed based on a literature review, followed by one-to-one interviews of 50 patients with psoriasis conducted by trained psychologists. The interview transcripts were analysed, after which 56 items were retained and validated in a cohort of 569 patients. Four QualiPso subscales were derived from factor analysis. The first factor encompasses disturbances of social life, a key factor in HRQoL among psoriasis patients (Cronbach's alpha coefficient:  $\alpha=0.948$ ). The second factor assesses the impact of psoriasis on mental health ( $\alpha=0.932$ ). The third factor reflects concerns related to treatment outcomes ( $\alpha=0.873$ ), and the fourth factor is related to skin symptoms ( $\alpha=0.772$ ). The subscales are related but distinct, accounting for 60% of the common variance. In conclusion, the QualiPso questionnaire provides a reliable and valid measure of a patient's psychosocial well-being in relation to psoriasis. It also measures the impact of concerns related to treatment outcomes and skin symptoms, which have not been addressed previously by HRQoL research on psoriasis. Key words: psoriasis; quality of life; validation; questionnaire; health status indicator.**

(Accepted February 28, 2011.)

Acta Derm Venereol 2011; 91: 660–665.

Alain Taïeb, Service de Dermatologie et Dermatologie Pédiatrique, Centre de référence pour les maladies rares de la peau, Hôpital St André, 1 rue Jean Burguet, CHU de Bordeaux, FR-33075 Bordeaux, France. E-mail: alain.taieb@chu-bordeaux.fr

Psoriasis can significantly affect a patient's health-related quality of life (HRQoL) through specific recurring symptoms, such as itching, appearance issues, scaling, and inability to control the disease, that particularly affect daily activities and social functioning (1, 2). When lesions are visible to others, patients may be confronted with negative psychosocial reactions, such as stigmatization and negative judgements, which represent a significant burden on their social life (3–6). Psoriasis is associated with a

reduction in work productivity and social functioning, and with sexual dysfunction and depression (7–9). Subjective experience of psoriasis was found to be more accurately associated with decreased QoL than medical indicators of disease severity (10, 11). The psychosocial impact of the disease may thus explain the relatively high cost of this disease at both macro- and micro-economic levels.

Assessing HRQoL in psoriasis patients is critical for clinicians in order to improve patient care, therapeutic decisions and treatment management (12, 13). Several psoriasis-specific questionnaires have been developed and tested (14–20). The Psoriasis Disability Index (PDI) has been used extensively in clinical studies, but it does not investigate psychological disturbances associated with psoriasis, while these issues are commonly described and reported by patients (21, 22). The Psoriasis Life Stress Inventory (PLSI) provides a measure of the daily hassles of psychological stress associated with having to cope with everyday events in living with psoriasis (23), and thus assesses disease-related stress and not HRQoL.

The total number of participants to be included in a study population is *a priori* estimated following explanatory factorial analyses (EFA) guidelines. Some authors (24, 25) recommend a minimum subject-to-item ratio of at least 5:1 in EFA, but they also have stringent guidelines for when this ratio is acceptable, and they both note that higher ratios are generally better. The widely cited rule of thumb from Nunnally (26) is that the subject-to-item ratio for exploratory factor analysis should be at least 10:1 in order to obtain a satisfactory factorial model. The reliability and validity of the 17-item Psoriasis Quality of Life Questionnaire (PQLQ) were determined in a group of 156 patients with psoriasis (17). The PSORIQoL draft measure consisting of 45 items was completed by 148 patients, not even reaching a 5:1 ratio (20). The US version was constructed using 72 patients to determine reliability, internal consistency and construct validity (16). Similarly, the PDI was validated in a study of 32 patients (19), while its French version was validated in 23 patients. Given their sizes, these studies might have lacked the statistical power required to compute conservative reliability estimates. Addressing these methodological issues would require the validation of these

existing questionnaires in larger samples. However, this method might limit findings to pre-selected items. Furthermore, adapting existing questionnaires to patients of different languages and cultural backgrounds can be difficult. In the field of epilepsy, a study controlling for socio-demographic and clinical characteristics found significant differences in scores on the perceived impact of epilepsy on HRQoL and in the stigma score between several European countries (27). Thus, we decided to construct a new tool assessing HRQoL in patients with psoriasis (the QualiPso Questionnaire) using a large cohort of French patients with psoriasis.

## MATERIALS AND METHODS

### *Construction of the draft questionnaire*

The construction of the questionnaire QualiPso involved three steps. First, a comprehensive analysis of data from the literature on the QoL of psoriatic subjects was conducted. None of the previously available questionnaires was satisfactory, mainly because of their limited psychometric qualities. The second step was to investigate the subjective disturbances related to disease and treatment by psoriatic patients in their daily life. Accordingly, 50 psoriasis patients, representative of the overall adult psoriatic population for age and gender, participated in a recorded, semi-structured exploratory interview based on open questions (“Tell me how your skin disorder developed?”, “What are the consequences of psoriasis on your everyday life?”, etc.). A thematic analysis of the content of patients’ answers (terms, sentences and all elements of speech) provided a list of items related to disease and treatment. They were classified into six thematic categories by two psychologists: social activities (12 items, from item 1 to item 12, e.g. visibility of lesions, clothing constraints, feeling of stigmatization, avoidance of public places and isolation), daily activities (6 items, from item 13 to 18, e.g. wearing gloves in order to avoid staining oneself or others, not being able to go to swimming pools or to the beach), perceived treatment outcome (6 items, from item 19 to 24; e.g. feeling that therapy is not efficient, that the disease is getting worse), treatment adverse effects (5 items, from item 25 to 29, e.g. need for repeated treatments, creams, ointments, malodorous baths), physical functioning (11 items, from item 30 to 40, e.g. itching, scaling, pain, etc.) and mental health (16 items, from item 41 to 56, e.g. stress, anxiety, discouragement, feeling dirty). A second classification was performed by a panel of four dermatologists and one academic psychologist. It reached a high level of agreement with the first classification. The third step was the construction of the questionnaire. A first draft of the questionnaire comprised 56 items. A test was carried out on 30 psoriasis subjects in order to check that the items were easily understood and that their formulation was not a cause of bias (wrong interpretation, misunderstanding).

### *Recruitment of participants and data collection*

The study protocol was approved by the local research ethics committee and informed consent was obtained from all participants. All patients aged 18–75 years diagnosed with psoriasis who attended the dermatology clinics at 7 hospitals located in Bordeaux and Libourne (3), Metz (2), Lille (1) and Toulouse (1) between April 2006 and December 2007 were eligible. The exclusion criteria were previous or current malignancy, current psychiatric disorder, obvious intellectual impairment, and inability to communicate in French. After obtaining informed consent, medical data adapted

from the Salford score (28) was collected by a physician (MBG, CP, FT, YG and AT) and included duration of disease (in years), type of psoriasis (plaque; guttate; nail; arthritic; other), previous treatments, current therapy (yes/no), and Psoriasis Activity and Severity Index (PASI) scores (assessed in three centres). Socio-demographic data were collected after each consultation by a trained psychologist during semi-structured interviews. They included gender, age (in years), educational level (high-school undergraduate, high-school degree, college degree), marital status (living alone/living in couple), occupational status (professionally active, retired, unemployed), and monthly income.

### *Measures*

**QualiPso draft questionnaire.** The 56-item draft questionnaire was administered in combination with other validated questionnaires assessing QoL and psychological distress.

**Medical Outcome Survey Short Form-36.** QoL was assessed with the French version of the SF-36, a multipurpose, 36-item survey that measures eight domains of health: physical functioning, role limitations due to physical health, bodily pain, general health perceptions, vitality, social functioning, role limitations due to emotional problems, and mental health. It yields scale scores for each of these 8 health domains, a lower score indicating a poorer QoL. The questionnaire has been previously validated in French (29).

**General Health Questionnaire-12.** Psychological distress was evaluated using the French version of the General Health Questionnaire-12 (GHQ12), a self-evaluation tool developed by Goldberg & Williams (30) in order to identify psychiatric problems in subjects taken from the general population, or from patients attending health care facilities. The GHQ12 is a shortened version of 12 items that quantify the level of subjective psychological suffering on various dimensions. It defines whether or not a given case can be categorized as pathological on the basis of threshold scores and investigates somatic symptoms, anxiety, insomnia, social dysfunction, and depression. Each item is graded 0 (not present) to 3 (maximum), and total scores range from 0 (no psychological distress) to 36 (high level of psychological distress).

**Hospital Anxiety Depression Scale.** Psychological distress was assessed using the French version (31) of the Hospital Anxiety and Depression Scale (HADS), which is widely used to measure psychological morbidity in patients with a variety of medical and psychological conditions (32–34). The HADS consists of 14 items, 7 on the anxiety subscale (HADS-A) and 7 on the depression subscale (HADS-D). Each item is graded 0 (not present) to 3 (maximum), and total scores range from 0 (no anxiety/depression) to 21 (high level of anxiety/depression).

**VQ-Dermato.** The VQ-Dermato is the first valid and reliable dermatology-specific HRQoL instrument in French, and the first based on the concept of chronic skin disorders (35), but it was not specifically designed to assess HRQoL disturbances in relation with psoriasis. It includes 28 items that measure several QoL domains, namely: self-perception, daily living activities, mood state, social functioning, leisure activity, treatment-induced restrictions and physical discomfort. A strong correlation has been found between some dimensions of the VQ-Dermato and some dimensions of the SF-36; e.g. the physical symptoms dimension from the VQ-Dermato (“discomfort”) with the equivalent dimension from the SF-36 (“bodily pain”); the physical capacity dimension of the VQ-Dermato (“daily living activity”) with the equivalent dimensions of the SF-36 (“physical functioning”, “role-physical” and “vitality”). Each question of VD-Dermato is given equal weighting. For each individual, the score of each of the 7 dimensions is obtained by computing the mean of the item scores of the dimension, a lower score indicating a poorer QoL.

### Statistical analyses

The goodness-of-fit Kolmogorov-Smirnov test showed that the distributions of all QualiPso subscales differed significantly from normality ( $p < 0.001$ ). Factors were estimated using an Unweighted Least-Square factorial analysis. This method was found to provide accurate and conservative parameter estimates when using ordinal data (36). Factor analysis was followed by a Promax rotation, a non-orthogonal (oblique) solution in which the factors are allowed to be correlated. This item reduction method established which of the provisional 56 items in QualiPso belonged to domains or conceptual areas and which items should be maintained. Items were deleted if they loaded on two or more factors, or if they exhibited a correlation coefficient of less than 0.40 with their own factor. Interpretation and naming of these factors were based on the consensus of the research team. Internal consistency reliability was assessed by computing Cronbach's  $\alpha$  coefficient (considered satisfactory if higher than or equal to  $\geq 0.70$ ). Correlations were computed with the non-parametric Spearman's correlation test. Test-retest reliability was assessed by computing intra-class correlation between QualiPso scores at baseline and 2 weeks thereafter, while item-scale validity was assessed by computing correlations between each item and the total score of the factor to which it belongs after having been removed from it (considered satisfactory if item-scale correlation achieved a value higher than or equal to 0.40), and relationships between QualiPso factors were assessed by computing inter-scale correlations in order to show that factors are related but distinct.

Convergent validity was examined by analysing the correlation between QualiPso scores and the component summary of the SF-36 and VQ-Dermato assessing the same conceptual HRQoL domains. We expected that patients who scored higher on QualiPso subscales would have higher scores on subscale scores of the SF-36 and VQ-Dermato assessing the same HRQoL concept. Divergent validity was examined by analysing the correlation between QualiPso subscale scores and the component summary of the SF-36 and VQ-Dermato assessing different conceptual HRQoL domains. Low correlations were expected between these scales. We also expected to see moderate-to-high negative correlations between QualiPso and HADS and GHQ-12 scores, as HRQoL has been shown to be negatively related to psychological distress in previous studies. Test-retest reliability was examined by analysing the intra-class correlation (ICC) between QualiPso subscale scores assessed in a sub-sample of 70 patients who attended a consultation 2 weeks after a first assessment. ICC of a given item in the same individual obtained at two consecutive assessments measures the ratio of its variance over the total variance. It can thus be used to estimate the stability of measure over time (test-retest reliability) if the time interval between HRQoL measurements is reasonably short. Accordingly, data from second assessments was dropped from analysis when time between two assessments exceeded 2 weeks ( $n = 499$ ).

Patients were divided into 3 groups according to the severity of their disease, as assessed with the PASI score (low:  $< 7$ ; moderate: 7–12, high:  $> 12$ ) and construct validity was investigated by comparing QualiPso subscale scores between the 3 groups with one-way analysis of variance (ANOVA). Bonferroni *post-hoc* tests were subsequently used to compare means. Based on the previous findings that disease severity may affect patients' HRQoL in various diseases, we expected that higher PASI scores, indicating a higher disease severity, would be associated with lower QualiPso scores. For all tests, a significance level of 0.05 was used.

## RESULTS

Among the 682 patients with psoriasis who were initially approached, 569 agreed to participate in the study

(83%). Refusals to participate were mainly due to lack of time (59%) and absence of interest (41%). The study population is described in Table I. Most patients were professionally active (55.2%) or retired (27.4%), were living with a partner (63.3%) and had plaque psoriasis (72.8%). The PASI score was available in 289 patients (50.8%) and showed that most patients (72.6%) had a low-to-moderate disease severity. A second HRQoL assessment was performed 2 weeks after the first in 70 patients (13% of the study population). The overall study design is presented in Fig. 1.

Preliminary analyses for factor reduction were performed and 16 of the initial 56 items were deleted since they loaded relatively high on more than one factor or relatively low on all factors. One item was deleted because of ambiguous wording. Unweighted least-square exploratory factorial analysis followed by a Promax rotation was performed on the remaining 39 items. Eigen values for the first 5 factors were 12.5, 7.7, 2.0, 1.1 and 0.92, suggesting a 4-factor solution explaining 59.9% of the common variance of the data (factor number 1: 32.2%; number 2: 19.9%; number 3: 5.2%; and number 4: 2.2%).

Items were accordingly grouped into 4 multi-item scales (Table SI: factor loadings between items (rows) and QualiPso factors (columns) estimated from factor analysis (available from: <http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1137>)). The

Table I. Participants' characteristics ( $n = 569$ )

Variables	<i>n</i> (%)
Male gender	258 (45.3)
Age (years)	
<40	175 (30.7)
40–60	232 (40.8)
>60	162 (28.5)
Marital status	
Single/divorced/widow	209 (36.7)
Living with a partner	360 (63.3)
Educational level	
Secondary school or less	452 (79.4)
University/further education	117 (20.6)
Occupational status	
Professionally active	314 (55.2)
Unemployed	99 (17.4)
Retired	156 (27.4)
Income (Euros per month)	
<1000	89 (15.6)
$\geq 1000$	480 (84.4)
Current therapy	480 (80.8)
Type of psoriasis	
Plaques	414 (72.8)
Guttate	24 (4.2)
Nail	36 (6.3)
Arthritic	5 (0.9)
Others <sup>a</sup>	19 (3.3)
Mixed	71 (12.5)
Psoriasis Area and Severity Index ( $n = 289$ )	
<7 (low severity)	164 (56.7)
7–12 (moderate severity)	46 (15.9)
>12 (high severity)	79 (27.4)

<sup>a</sup>Palmoplantar, folds, pustular, arthritic with minimal cutaneous change.

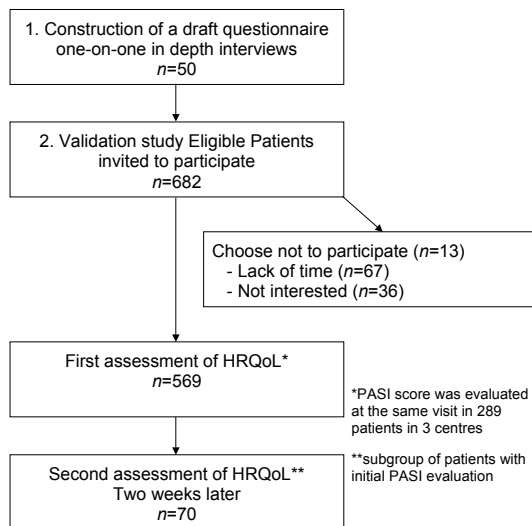


Fig. 1. QualiPso study: overall design. HRQoL: health-related quality of life; PASI: Psoriasis Area and Severity Index.

first factor comprised items originally related to social function (items 1–11), daily activities (items 15 and 17), treatment outcomes (item 20), adverse effects (items 26 and 29) and physical function (items 30, 37 and 40). It was interpreted as a factor expressing social life (SL). The second factor comprised items originally related to mental health (MH) (items 41–44, 47, and 49–55) and was interpreted accordingly. The third factor comprised items related to treatment outcomes (TO) (items 19, 21, 22, 24) and was interpreted accordingly. The fourth factor comprised items originally related to physical function (items 31, 35, 38) and was interpreted as a factor expressing disturbances resulting from skin symptoms (SkS). The 4 factors exceeded the minimum standard of 0.70 for internal consistency as assessed by the Cronbach's alpha coefficient:  $\alpha=0.948$  (SL);  $\alpha=0.932$  (MH),  $\alpha=0.873$  (TO) and  $\alpha=0.772$  (SkS). A summary score was computed for each factor.

Interscale correlations between SL, MH, TO, and SkS (Table SII; available from: <http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1137>), assessed twice at a 2-week interval in the same patient, were low to moderate (ranging from 0.358 to 0.468), showing that these factors were related but distinct. Correlations between SL and other factors were low to absent, ranging from 0.065 to 0.210. QualiPso was measured twice at a maximum time interval of 2 weeks in 70 patients, and intra-class correlations were satisfactory (SL: 0.735;  $p<0.001$ ; MH: 0.720,  $p<0.001$ ; TO: 0.718,  $p<0.001$ ; and SkS: 0.709,  $p<0.001$ ).

Item-scale validity was assessed by computing correlations between one item and the total score of their own factor computed without the considered item. All items of the QualiPso were correlated moderately with the total score of their own factor (SL: range=0.427–0.683;  $p<0.001$ ; MH: range=0.518–0.721,  $p<0.001$ ; TO: range=0.638–0.687;  $p<0.001$ ; and SkS: range=0.509–

0.655,  $p<0.001$ ) and were more correlated with the total score of their own factor than with the total score of any other QualiPso factor.

For convergent validity, all QualiPso factors correlated significantly and meaningfully with the SF-36 subscales (Table SIII: correlations between subscales from several validated questionnaires (rows) and the four factors of the QualiPso (columns) (available from: <http://www.medicaljournals.se/acta/content/?doi=10.2340/00015555-1137>)). The highest correlations were found between the MH factor of the QualiPso and those of the SF-36 ( $\rho=0.682$ ,  $p<0.01$ ), and between the SL factor of the QualiPso and social dimensions of the SF-36: social function:  $\rho=0.536$ ,  $p<0.01$ ; psychological role-limitation:  $\rho=0.516$ ,  $p<0.01$ ; and physical role limitation:  $\rho=0.445$ ,  $p<0.01$ . The QualiPso MH factor was also significantly correlated with SF-36 social functioning components: social function:  $\rho=0.510$ ,  $p<0.01$ ; psychological role-limitation:  $\rho=0.495$ ,  $p<0.01$ ; and physical role limitation:  $\rho=0.393$ ,  $p<0.01$ . Lower ( $\rho<0.30$ ) and non-significant relationships were observed between SF-36 subscales and other QualiPso factors (TO and SkS).

Correlations between the first two factors of the QualiPso and VQ-Dermato subscales were significant but low ( $\rho<0.40$ ). The highest correlations were found between the QualiPso SL factor and the VQ-Dermato Self-image ( $\rho=0.326$ ,  $p<0.01$ ) and psychological Well-being ( $\rho=0.309$ ,  $p<0.01$ ). Surprisingly, a negative relationship was observed between the QualiPso Social Life subscale and the VQ-Dermato Social functioning subscale ( $\rho=-0.188$ ,  $p<0.01$ ). GHQ-12 and HADS subscales correlated highly and negatively with the QualiPso MH factor, and to a lesser extent with other subscales.

Construct validity was investigated by comparing mean scores of each QualiPso factor between patients with different disease severity as assessed with the PASI score (Fig. 2). One-factor ANOVA showed a significant difference in SL mean scores according to disease severity ( $p<0.001$ ). The *post-hoc* test showed that patients with low disease severity had higher SL mean scores ( $66.8\pm 17.6$ ) than those with moderate ( $54.0\pm 19.6$ ;  $p<0.001$ ) or severe disease severity ( $47.4\pm 19.1$ ;  $p<0.001$ ). ANOVA showed significant differences in TO mean scores according to disease severity ( $p<0.05$ ). The *post-hoc* test showed that patients with low disease severity had higher TO mean scores ( $10.4\pm 4.3$ ) than those with moderate disease severity ( $8.7\pm 4.1$ ;  $p<0.04$ ).

## DISCUSSION

QualiPso subscales were found to be psychometrically robust, with excellent internal consistency and good item-scale, convergent, and construct validity. Further analysis showed that four related, but distinct, QualiPso factors account for 59.9% of the common variance. The

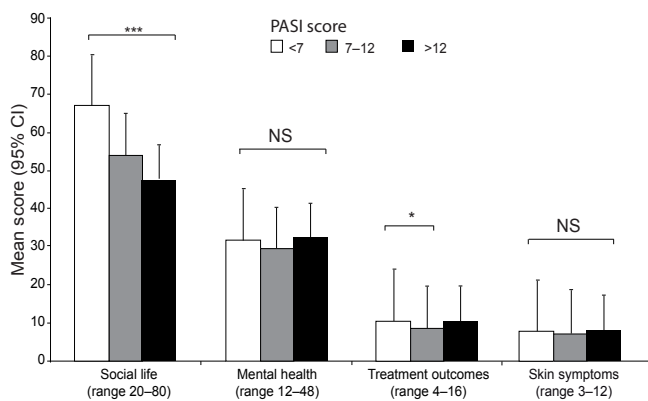


Fig. 2. QualiPso mean scores according to Psoriasis Area and Severity Index (PASI) score. Upper bar represent 95% confidence interval (CI). \*\*\* $p < 0.001$ ; \* $p < 0.001$ . NS: non significant. Differences were assessed with One Factor Analysis of Variance (ANOVA).

first factor encompasses an array of disturbances in social life and includes more than half of the selected items. The second factor assesses the impact of psoriasis on mental health. Our results show that psychological disturbances experienced by psoriasis patients include irritability, anxiety and depressive symptoms. Given the potential severity of such symptoms, their assessment in patients with psoriasis should not be neglected by dermatologists. Finally, the last two factors assessed actual concerns that might significantly disturb a patient's well-being: treatment outcome and skin symptoms (37–39). The absence of a factor related to physical functioning in the QualiPso constitutes a noticeable difference with other general and specific HRQoL measures. Although physical symptoms related to psoriasis were not considered as having an independent effect on HRQoL, some of them were included in the social life factor. One possible explanation is that severe somatic symptoms, such as having difficulties walking, standing, or having burning sensations, might be considered disturbing because of their limiting impact on social life. Further research is, however, needed to investigate this hypothesis.

The distinct factor structure of the QualiPso is supported by the item-scale validity tests, in which constituent items were more correlated with their own factors than with any other factors. Results regarding test-retest reliability indicate a satisfactory stability of responses over time. Regarding the convergent validity analyses, the social and mental components of the SF-36 were found to highly correlate with the QualiPso SL and MH factors. Because these scales measure the same concepts, significant and high correlations between scores were expected. Conversely, lower correlations were found between the social and mental components of the SF-36, and the QualiPso TO and SkS factors, as they assess dissimilar concepts. Lower correlations were also found between the “treatment” and “physical discomfort” components of the VQ-Dermato, and the QualiPso TO and SkS factors, although they might be

considered as more related. This might indicate that other general and specific HRQoL tools did not encompass these specific concerns related to treatment efficacy and skin symptoms. The QualiPso might accordingly fill a gap that was not addressed previously.

It must be stressed that QualiPso factors correlated poorly with the VQ-Dermato, a skin disease-specific HRQoL questionnaire. One possible explanation might be that several concepts assessed in the VQ-Dermato as independent factors (i.e. leisure or self-image) are included in broader factors (Social life or Mental Health) in the QualiPso. However, the QualiPso SL subscale was negatively related to the social component of the VQ-Dermato, although they both assess the disease's impact on social activity. Further analyses showed that the social disturbances attributable to psoriasis are assessed in terms of intensity in 4 out of 5 items in the VQ-Dermato, and in terms of frequency in 18 out of 20 items in the QualiPso. Item distributions showed that social disturbances were rated low in intensity, but high in frequency, thus explaining the negative relationship between QualiPso and VQ-Dermato social components. Our findings suggest that HRQoL disturbances were reported as low in intensity, but high in frequency, a result consistent with the fact that most participants were under treatment during the study period, thus limiting the severity of the chronic symptoms of the disease. Construct validity assessed with the PASI scores confirmed that psoriasis affects a patient's HRQoL mainly through significant disturbances in social life. Indeed, the QualiPso SL factor score was significantly reduced in patients with the highest PASI scores while psychological well-being was not affected by disease severity.

Limitations of the study: validation of any instrument is an ongoing process and the current validation is a first step towards a more comprehensive validation of the QualiPso. Although promising, our preliminary validation requires confirmation in several areas, such as the evaluation of the responsiveness and sensitivity of the QualiPso to changes over time, and in incorporating it into routine clinical assessments and trials to improve the understanding and interpretation of individual patient's scores. The validation of a short-form questionnaire is also required to facilitate its use during routine medical care.

Nonetheless, the present findings suggest that the QualiPso provides a reliable and valid measure of patients' psychosocial well-being in relation to psoriasis. It assesses the impact of disease on social and psychological functioning, in line with most HRQoL questionnaires. But it also measures the impact of concerns related to treatment outcomes and skin symptoms, which have not been previously addressed in HRQoL research on psoriasis. This questionnaire could therefore be a useful tool to investigate changes over time within and between different psoriasis therapies in clinical practice or research.

## ACKNOWLEDGEMENTS

The study was funded by the Programme Hospitalier de Recherche Clinique (PHRC) 2002 with additional funding provided by Merck Serono France and Abbott France. We thank the Association Française de Lutte Contre le Psoriasis (AFLCLP) for help with the project, especially for facilitating patient recruitment.

*The authors declare no conflict of interest.*

## REFERENCES

- de Korte J, Sprangers MA, Mommers FM, Bos JD. Quality of life in patients with psoriasis: a systematic literature review. *J Investig Dermatol Symp Proc* 2004; 9: 140–147.
- Heydendael VM, de Borgie CA, Spuls PI, Bossuyt PM, Bos JD, de Rie MA. The burden of psoriasis is not determined by disease severity only. *J Investig Dermatol Symp Proc* 2004; 9: 131–135.
- Wahl AK, Gjengedal E, Hanestad BR. The bodily suffering of living with severe psoriasis: in-depth interviews with 22 hospitalized patients with psoriasis. *Qual Health Res* 2002; 12: 250–261.
- Vardy D, Besser A, Amir M, Gesthalter B, Biton A, Buskila D. Experiences of stigmatization play a role in mediating the impact of disease severity on quality of life in psoriasis patients. *Br J Dermatol* 2002; 147: 736–742.
- Kimball AB, Jacobson C, Weiss S, Vreeland MG, Wu Y. The psychosocial burden of psoriasis. *Am J Clin Dermatol* 2005; 6: 383–392.
- Jobling R, Naldi L. Assessing the impact of psoriasis and the relevance of qualitative research. *J Invest Dermatol* 2006; 126: 1438–1440.
- Türel Ermertcan A, Temeltaş G, Deveci A, Dinç G, Güler HB, Öztürkcan S. Sexual dysfunction in patients with psoriasis. *J Dermatol* 2006; 33: 772–778.
- Schmitt JM, Ford DE. Role of depression in quality of life for patients with psoriasis. *Dermatology* 2007; 215: 17–27.
- Mukhtar R, Choi J, Koo JY. Quality-of-life issues in psoriasis. *Dermatol Clin* 2004; 22: 389–395, viii.
- Psoriasis Research on Vital Experiences (IMPROVE) Investigators. Measures of clinical severity, quality of life, and psychological distress in patients with psoriasis: a cluster analysis. *J Invest Dermatol* 2004; 122: 602–607.
- Perrott SB, Murray AH, Lowe J, Mathieson CM. The psychosocial impact of psoriasis: physical severity, quality of life, and stigmatization. *Physiol Behav* 2000; 70: 567–571.
- Feldman S, Behnam SM, Behnam SE, Koo JY. Involving the patient: impact of inflammatory skin disease and patient-focused care. *J Am Acad Dermatol* 2005; 53: S78–S85.
- Rapp SR, Feldman SR. The promise and challenge of new biological treatments for psoriasis: how do they impact quality of life? *Dermatol Ther* 2004; 17: 376–382.
- Shikhar R, Willian MK, Okun MM, Thompson CS, Revicki DA. The validity and responsiveness of three quality of life measures in the assessment of psoriasis patients: results of a phase II study. *Health Qual Life Outcomes* 2006; 4: 71.
- Papp KA, Henninger E. Safe psoriasis control: a new outcome measure for the composite assessment of the efficacy and safety of psoriasis treatment. *J Cutan Med Surg* 2005; 9: 276–283.
- McKenna SP, Lebowhl M, Kahler KN. Development of the US PSORIQoL: a psoriasis-specific measure of quality of life. *Int J Dermatol* 2005; 44: 462–469.
- Inanir I, Aydemir O, Gunduz K, Danaci AE, Turel A. Developing a quality of life instrument in patients with psoriasis: the Psoriasis Quality of Life Questionnaire (PQLQ). *Int J Dermatol* 2006; 45: 234–238.
- Evers AW, Duller P, van de Kerkhof PC, van der Valk PG, de Jong EM, Gerritsen MJ, et al. The Impact of Chronic Skin Disease on Daily Life (ISDL): a generic and dermatology-specific health instrument. *Br J Dermatol* 2008; 158: 101–108.
- Finlay AY, Khan GK, Luscombe DK, Salek MS. Validation of Sickness Impact Profile and Psoriasis Disability Index in Psoriasis. *Br J Dermatol* 1990; 123: 751–756.
- McKenna SP, Cook SA, Whalley D, Doward LC, Richards HL, Griffiths CE, et al. Development of the PSORIQoL, a psoriasis-specific measure of quality of life designed for use in clinical practice and trials. *Br J Dermatol* 2003; 149: 323–331.
- Van Voorhees AS, Fried R. Depression and quality of life in psoriasis. *Postgrad Med* 2009; 121: 154–161.
- Magin P, Adams J, Heading G, Pond D, Smith W. The psychological sequelae of psoriasis: results of a qualitative study. *Psychol Health Med* 2009; 14: 150–161.
- Gupta MA, Gupta AK. The Psoriasis Life Stress Inventory: a preliminary index of psoriasis-related stress. *Acta Derm Venereol* 1995; 75: 240–243.
- Gorusch RL. Factor analysis (2nd edn). Hillsdale, NJ: Lawrence Erlbaum Associates, 1983.
- Hatcher L. A Step-by-step approach to using the SAS® system for factor analysis and structural equation modeling. Cary, NC: SAS Institute, Inc., 1994.
- Nunnally JC. Psychometric theory (2nd edn). New York: McGraw Hill, 1978.
- Buck D, Jacoby A, Baker GA, Ley H, Steen N. Cross-cultural differences in health-related quality of life of people with epilepsy: findings from a European study. *Qual Life Res* 1999; 8: 675–685.
- Kirby B, Fortune DG, Bhushan M, Chalmers RJ, Griffiths CE. The Salford Psoriasis Index: an holistic measure of psoriasis severity. *Br J Dermatol* 2000; 142: 728–732.
- Perneger TV, Leplege A, Etter JF, Rougemont A. Validation of a French-language version of the MOS 36-Item Short Form Health Survey (SF-36) in young healthy adults. *J Clin Epidemiol* 1995; 48: 1051–1060.
- Goldberg DP, Williams P. A user's guide to the General Health questionnaire. Windsor: NFER-Nelson, 1988.
- Lépine JP. Hospital anxiety and depression scale. Evaluation Clinique Standardisée en Psychiatrie ed. J.D. Guelfi., Paris: Editions Médicales Pierre Fabre, 1996: p. 367–370.
- Johnston M, Pollard B, Hennessey P. Construct validation of the hospital anxiety and depression scale with clinical populations. *J Psychosom Res* 2000; 48: 579–584.
- Bjelland I, Dahl AA, Haug TT, Neckelmann D. The validity of the Hospital Anxiety and Depression Scale. An updated literature review. *J Psychosom Res* 2002; 52: 69–77.
- Marinus J, Leentjens AF, Visser M, Stiggelbout AM, van Hilten JJ. Evaluation of the hospital anxiety and depression scale in patients with Parkinson's disease. *Clin Neuropharmacol* 2002; 25: 318–324.
- Forero CG, Maydeu-Olivares A, D Gallardo-Pujol. Factor analysis with ordinal indicators: A Monte Carlo study comparing DWLS and ULS estimation. *Struct Equat Model* 2009; 16: 625–641.
- Grob JJ, Auquier P, Martin S, Lançon C, Bonerandi JJ. Development and validation of a quality of life measurement for chronic skin disorders in French: VQ-Dermato. *Dermatology* 1999; 199: 213–222.
- Verhoeven EW, Klerk S, Kraaimaat FW, van de Kerkhof PC, de Jong EM, Evers AW. Biopsychosocial mechanisms of chronic itch in patients with skin diseases: a review. *Acta Derm Venereol* 2008; 88: 211–218.
- Dalgard F, Svensson A, Sundby J, Dalgard OS. Self-reported skin morbidity and mental health. A population survey among adults in a Norwegian city. *Br J Dermatol* 2005; 153: 145–149.
- Basra MK, Finlay AY. The family impact of skin diseases: the Greater Patient concept. *Br J Dermatol* 2007; 156: 929–937.