

Individual Burden of Psoriasis (I-BOP): Building and Validation of a New Scoring Tool for Patients with Psoriasis

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Background: Psoriasis impacts independently of its severity on patients' lifestyle and quality of life (QoL).

Aim: To build a tool for assessing the patient-reported psoriasis burden.

Methods: An expert group created a questionnaire using a standardized methodology building questionnaires assessing quality of life issues. The questionnaire was translated from French into a cultural and linguistically validated US English version.

Results: A conceptual questionnaire of 54 questions was created. The confirmatory analyses resulted in a 10-feature questionnaire divided into 4 internally consistent domains with a Cronbach's alpha coefficient of 0.9. It was reproducible and highly reliable. It correlated well with the Dermatology Life Quality Index (DLQI), Perceived Stress Scale (PSS), and SF-12 mental and SF12 physical scores.

Conclusion: This tool allows for the first time to assess the burden of psoriasis patients. Its use may allow improving medical and nonmedical patient care, thus improving their daily life.

Keywords: disease burden, psoriasis, quality of life, questionnaire, standardized method

Introduction

Psoriasis is a chronic condition requiring life-long treatment. Its worldwide prevalence has been estimated at approximately 1–3%.¹ It is mainly observed on the skin but may also affect joints. Up to 42% of patients with psoriasis also have associated psoriatic arthritis.^{2,3} Moreover, an increased risk of obesity, diabetes, and cardiovascular events has been reported for psoriasis patients.^{4,5}

But, psoriasis may also cause a psychiatric burden. In psoriasis patients, the appearance and discomfort of lesions, especially if visible, negatively impact self-esteem and quality of life (QoL) and may cause depression.^{6–9} Patients with psoriasis are tempted to cover visible zones attempted, may suffer from sexual problems, and avoid physical activities and may feel ashamed, anxious, and frustrated.^{6,10} As a result, treatment efficacy maybe impacted through a lack of compliance, starting a vicious circle.¹¹ Therefore, identifying the most vulnerable patients may not only allow managing these psychological issues but also improve their adherence to treatment.¹²

“Global Disease Burden” was defined for the first time by the World Health Organization.^{13,14} Today, the focus of burden also applies to the individual disease

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burden, comprising psychological, social, economic, and physical features. In psoriasis, infantile haemangioma, hereditary ichthyoses, atopic dermatitis, vitiligo, albinism and palmoplantar keratoderma, individual disease burden has already been evaluated.^{15–21}

According to our literature search, no specific instrument exists to assess the burden experienced by psoriasis patients. However, such a tool may be useful for both patients and clinicians in charge of patient management. This instrument may, firstly, help to describe patient perceptions and, secondly, allow monitoring any changes in medical and non-medical care.

The aim of the present work was to build a self-administered tool allowing assessing the individual disease burden in psoriasis patients.

Methodology

Compiling this self-administered questionnaire did not require the approval of national health authorities. The work received approval from the national Ethics committee in July 2018. According to French regulations, no written informed consent was to be obtained from participating patients.

The tool was built following a standard methodology for creating QoL questionnaires.²² A group of experts in the design and development of questionnaires, such as health-care professionals (physicians and public-health specialists) as well as medical experts in psoriasis were created to validate the questionnaire.

A question and answer format was used. The response format followed a 7-point Likert scale: “never” (0), “rarely” (1), “sometimes” (2), “often” (3), “very often” (4), “constantly” (5) “not concerned” (0). The majority of all questions included the wording “due to my psoriasis”. This was to avoid any confusion with changes in perception due to symptoms related to comorbidities.

Conception

Prior to building the questionnaire, the authors conducted a literature research on PubMed to identify published work about questionnaires or scoring systems related to psoriasis. The authors performed several interviews with dermatologists, patient-reported outcome (PRO) experts, and psoriasis patients to collect the perception and complaints of patients as well as data for the initial wording. Based on the wording reports a list of features was prepared. These features were reformulated as easy-to-understandable questions.

Interviews ensured a large recruitment and a coherent diversity of participants regarding their geographical location, age, and sociological status; questionnaires were used to clinically confirm psoriasis. The working group semantically analysed the initial phrasing and finalised the list of questions. If similarities were too strong then questions were combined.

As a result, a semi-structured “Individual Burden of Psoriasis (I-BOP)” questionnaire using closed-ended questions was built. This tool covered relationships with others, economic consequences, impact on work, impact on daily life, on sexuality and libido.

Development

The conceptual questionnaire was administered to a random sample of psoriasis patients selected at the author’s practice facilities. Questionnaires were analysed using an exploratory factor analysis to reveal latent constructs. Each feature was assigned to its respective domain or dimension.

Questions with a too low or too high inter-feature correlation (lower than 0.3 or higher than 0.9) were eliminated. A Keyser Meyer Odin (KMO) analysis was conducted ensuring an appropriate factor analysis (KMO over 0.4 for all features).

Moreover, an exploratory factor analysis was done using a promax rotation to determine the domain or dimension of each feature.²³ Features with a low factor loading (lower than 0.4) or a high cross factor loading (higher than 0.2) were excluded.

Validation

Internal validation

Features were tested for their the homogeneity in each dimension using the Cronbach’s alpha coefficient.²⁴ Higher scores (>0.7) suggest good homogeneity.

A confirmatory analysis for the higher-order factor was done in order to demonstrate the questionnaire’s unidimensionality. The model’s suitability was measured using several criteria, including the Bentler comparative fit index and the Bentler-Bonett non-normed fit index both were set at >0.90.²⁵ The root mean square error of approximation (RMSEA) was set at 0.05 or at the very least <0.08, with 0.05 being the confidence interval.

External Validation

All participants were asked to complete the 12-feature Short Form Health Survey (SF12), Dermatology Life

Quality Index (DLQI) questionnaire and Perceived Stress Scale (PSS).^{26–28} The SF12 is a short version of the SF-36.²⁹ Based on 12 questions, a physical composite score (PCS, SF-12P) and mental composite score (MCS, SF-12M) were calculated. The DLQI questionnaire assesses the impact of skin diseases and associated treatments on patient QoL in patients aged above 16 years. The PSS measures the perception of stress.

A Pearson correlation was calculated assessing the reliability between the I-BOP questionnaire and these 3 questionnaires.

All data were analysed using R software version 3.5.3 for Windows, with a significance level set at 0.05.

Test–Retest Validation

Test–retest analyses assess reproducibility. Participants completed the I-BOP questionnaire twice within a 2-week interval. Answers were compared and the reliability of measurements was confirmed.

Translation, Cross-Cultural Adaptation, and Cognitive Debriefing

A US English-language version according to the recommendations of the ISPOR task force was issued.³⁰ The different conception, development, and validation steps are summarized in (Table 1).

Results

Conception

The literature review identified 11 psoriasis-related questionnaires and scoring systems.^{31–41} Verbal exchanges and several face-to-face meetings took place between dermatologists, psychologists, social workers, and patient-reported outcome (PRO) experts. In addition, the perception and complaints regarding psoriasis of 20 participants served for the conception of the tool. As a result, an initial verbatim, leading to a 54-feature conceptual questionnaire was created. Questions were categorized into relationships with others, economic consequences, impact on work and impact on everyday life and formatted using the 7-answer Likert scale.

Development

In total, 377 patients who attended the author's clinics and patients of the Reso-Pso network were invited to test the conceptual questionnaire. Patients with psoriatic arthritis were not considered for statistical analyses. Thus, 208 patients were suitable for testing the tool.

Table 1 Principles of Good Practice for the Translation and Cultural Adaptation Process for Patient-Reported Outcomes (PRO) Measures

Stage	Details
Preparation	Evaluation of the source text from a linguistic and cultural point of view including definition of concepts
Forward translations	Forward translation into the required target language by two independent translators
Reconciliation	Comparison of the two forward translations to provide the best adapted and to produce a draft version of the text
Back translation	Translation of the draft forward translation back into the targeted language without reference to the original language
Back translation review	Comparison of the original text and the back translation to verify if changes are required to the draft forward version
Analysis and implementation of back translation review report	Analysis of the back translation review report to verify if changes are required to draft forward version
Pilot testing	Clinical review and cognitive debriefing
Review of cognitive debriefing or clinical review results	Review of results from the cognitive debriefing or clinical review to identify translation modifications necessary for improvement

Note: Data from Wild et al.³⁰

Once all questionnaires were collected and evaluated, the working group performed a semantic analysis of the initial conceptual questionnaire. Non-discriminating questions (questions for which more than 90% of the responders, regardless of sex or age, provided identical answers) and questions for which wording was considered non-pertinent were eliminated, resulting in an 18-feature questionnaire.

Following this selection, an inter-feature correlation matrix was created in order to compile a condensed questionnaire. Results from this matrix correlation eliminated 4 more questions which all presented with an inter-feature correlation factor of less than 0.3 or of more than 0.9, resulting in a 14-feature questionnaire.

Exploratory Factor Analysis

All KMO scores confirmed that the dataset is suitable for conducting an EFA (exploratory factor analysis).

The scree plot obtained through the EFA determined 2 pertinent dimensions (Figure 1).

Moreover, this analysis eliminated questions with a loading factor of less than 0.5 or with a cross factor of more than 0.25 (Table 2). As a result, 4 more questions were eliminated from the questionnaire, leading to a 10-feature questionnaire. The semantic analysis identified 2 domains: “personal perception”, covering 6 questions and “perception of others” covering 4 questions (Figure 2).

Validation

The resulting 10-feature questionnaire was distributed together with SF-12, DLQI and PSS questionnaires to 623 patients attending the authors’ facilities and members of the Reso-Pso network; answers from patients with psoriatic arthritis were not considered. Thus, 550 psoriasis patients participated in this internal validation.

Internal Validation

The higher-order factor analysis resulted in a practical suitability index of 0.845404, with a Bentler comparative fit index (CFI) of 0.0.8644876, Bentler-Bonett non-normed fit index of 0.8549433, and an RMSEA index of 0.1444259

(95% CI [0.1323132; 0.1568747]). Based on these indicators and according to Kenny and McCoach, the model was proven to be correctly adjusted and suitable; the 2 dimensions could be grouped together into one single overall score.⁴²

The Cronbach’s alpha coefficient was 0.9 for the entire questionnaire, confirming its excellent internal coherence.

External Validation

The questionnaire highly correlated with the SF-12 (SF-12P: -0.12 and SF-12M: -0.49), DLQI (0.77) and PSS (0.47) questionnaires.

Test–Retest Analysis

The test–retest reliability was made by 58 participants at Day 0 and Day 10; 47 usable test results were obtained; for 11 participants only the questionnaire for Day 0 was collected. Reproducibility was very good; the intra-class correlation of each dimension exceeded 85% for each domain, the total intra-class correlation (ICC) score was 0.98 with a CI 95% of [0.952, 0.991]. A first scale ICC reached 0.986 with a CI 95% of [0.969, 0.994] and the second scale ICC was 0.959 with a CI 95% of [0.91, 0.984].

Cognitive Debriefing, Translation, and Cross-Cultural Adaptation

Cognitive debriefing required no changes of the wording. The original French version was translated and underwent

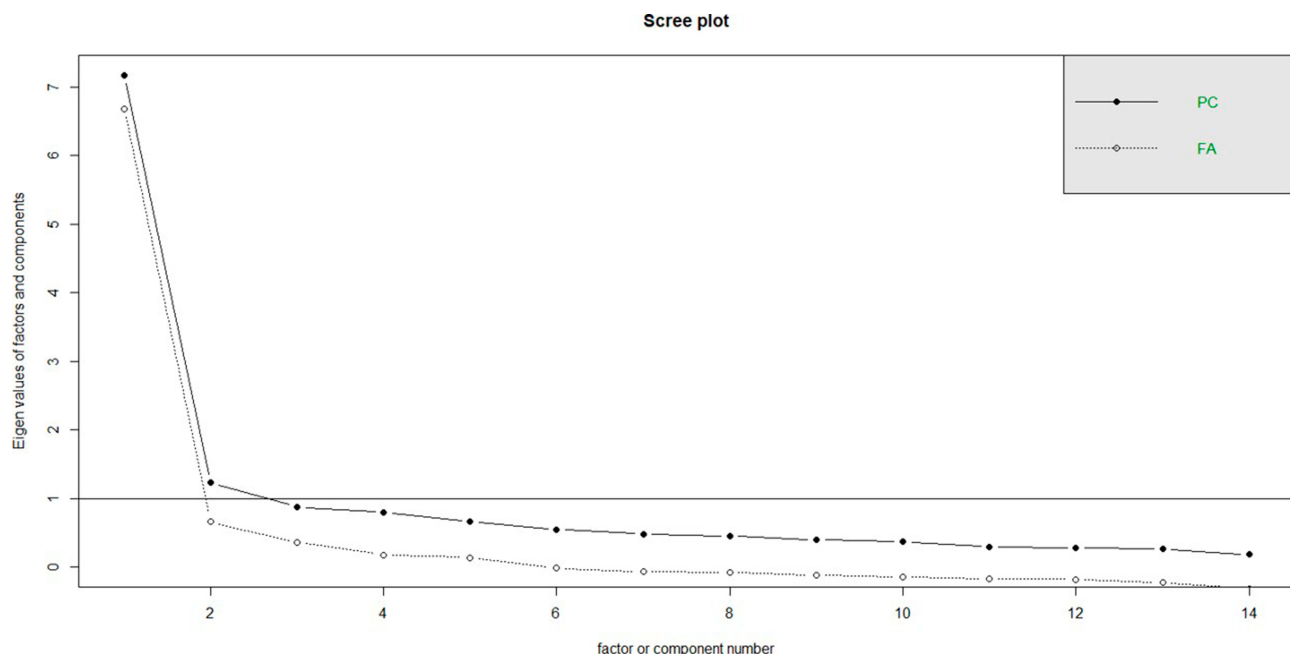


Figure 1 Exploratory factor analysis: scree plot. The scree plot served to determine the number of dimensions.

Abbreviations: FA, factor analysis; PC, principal component.

Table 2 Exploratory Factor Analysis: Questions with a Loading Factor of Less Than 0.5 or with a Cross Factor of More Than 0.25

	MR1	MR2
Question 1	0.38	0.27
Question 2	0.85	-0.03
Question 3	-0.15	0.77
Question 4	-0.13	0.87
Question 5	0.82	-0.19
Question 6	0.64	0.06
Question 7	0.73	0.05
Question 8	0.19	0.42
Question 9	0.08	0.59
Question 10	0.06	0.64
Question 11	0.50	0.33
Question 12	0.55	0.29
Question 13	0.44	0.40
Question 14	0.92	-0.06

Abbreviation: MR, minimum rank.

linguistic and cultural validation into US English. The final, validated version is given in (Table 3).

Scoring

Summing up scores for each of the 10 questions allowed calculating the total tool score. This was defined in the

mentioned method description, with “never” or “not applicable” scoring 0, “rarely” 1, “sometimes” 2, “often” 3, “very often” 4, and “constantly” 5 and with an I-BOP total score of “0” = no impact to “70” = highest possible impact.

Discussion and Conclusion

Psoriasis impacts independently of its severity on the patient’s lifestyle and QoL.⁴³ To the best of our knowledge, to date, no tool exists assessing the overall burden of psoriasis patients. Here we provide an easy-to-use tool allowing assessing the individual psoriasis burden. It is currently available in French and US English.

This newly developed burden assessment tool is robust with an internal consistency exceeding the minimum reliability criterion of 0.90 for an individual analysis.

The issue of individual disease burden is increasingly investigated especially for chronic skin diseases known for psychosocially affecting the patient. It is well established that “Individual burden” is responsible for disability caused by diseases. It covers psychological, physical, social, and economic factors, impacting QoL, social interaction, everyday life, and medical care. Using questionnaires allows evaluating this burden.^{15–17,19,22}

Advances made in QoL research over the last decades allowed health-care givers and regulatory agencies facing

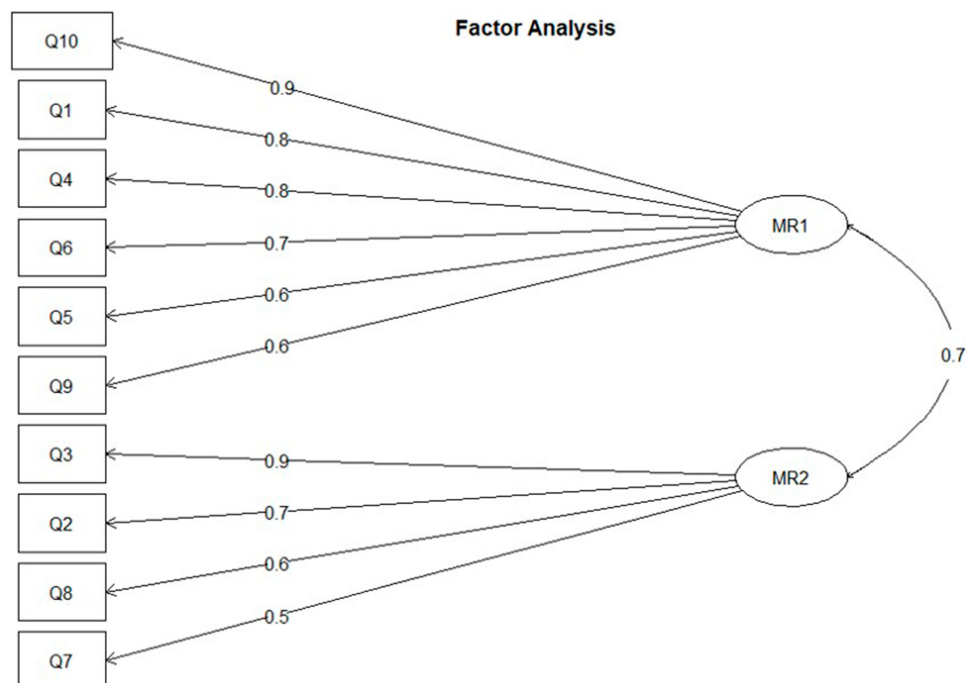


Figure 2 Exploratory factor analysis: Semantic analysis. The exploratory factor analysis allowed determining of domains: Domain I (MR1): own perception and Domain 2 (MR2): perception of others.

Table 3 10-Feature I-BOP Questionnaire

	Always	Very Often	Often	Sometimes	Rarely	Never	Not Applicable
Have you felt that your psoriasis is an aesthetic burden?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do you worry about your psoriasis flaring up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you worried that the marks or scars will be permanent?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has your psoriasis made you angry?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you felt discouraged because of your psoriasis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you been unhappy with your appearance because of your psoriasis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In your opinion, has your psoriasis had an impact on your sex life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you felt tired because of your psoriasis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you found it hard to work because of your psoriasis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Have you found it difficult to concentrate because of your psoriasis?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

multifaceted situations.¹⁶ In this context, Cohen et al prepared recommendations for basing all health-related QoL claims on rigorously designed studies.²⁷ The use of QOL questionnaires in clinical research is more and more frequent to achieve market access.¹⁹

In conclusion, the I-BOP questionnaire is a reliable tool. It may help to better appreciate the multidimensional nature of psoriasis. Moreover, it may help to better understand the individual burden of psoriasis patients and as such may play a key role in the decision-making process. Additional research to develop a version of the instrument for children in the near future is ongoing.

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Disclosure

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