

# QUALITY OF LIFE EVALUATION IN PSORIASIS PATIENTS STARTING A BIOLOGICAL TREATMENT: THE IMPORTANCE OF A MORE COMPREHENSIVE ASSESSMENT OF DISEASE BURDEN

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## ABSTRACT

Psoriasis is a chronic condition that has a significant negative impact on a patient's quality of life (QoL). Measures of the clinical severity of psoriasis alone may not reflect patients' perceptions of the impact of the disease on their lives. The aim of our study was to assess QoL in psoriasis patients who were candidates to receive one of the new biological treatments in order to obtain a more complete evaluation of the severity of the disease prior to treatment. A total of 180 patients were analysed, with all being affected by plaque-type psoriasis. The clinical severity of psoriasis was assessed by the Psoriasis Area and Severity Index, while QoL was assessed by three measures: the Dermatology Life Quality Index, the Skindex-29, and the Psoriasis Disability Index. Our results show how pervasive the impact of psoriasis is in patients who are candidates for the new biological treatments, and they further confirm the lack of a strong correlation between measures of clinical severity and QoL.

**Keywords:** Biological therapies, psoriasis, quality of life (QoL), questionnaire.

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## INTRODUCTION

Psoriasis is a chronic disease that affects 1-3% of the world's population, with an equal gender distribution.<sup>1,2</sup> It has a substantial physical, functional, and psycho-social impact on everyday life for most of those affected.<sup>3</sup> Recent investigations have shown that patients with psoriasis suffer as much disability as people with severe medical conditions such as cancer, arthritis, heart disease, diabetes, and depression.<sup>4-6</sup> In addition to frequent symptoms,<sup>7</sup> such as itching and pain, some patients experience joint involvement that may cause severe physical disability.

Acting as an organ of sensation, sexuality, and social interaction, the condition of the skin affects body-image and self-esteem, as well as aspects of social life such as participation and interaction at work or at school. Social rejection is a common feeling experienced by people with psoriasis. Several studies have described common reactions

to psoriasis as including embarrassment, impaired daily activities, anxiety, anger, and depression.<sup>8-10</sup> The presence of psoriasis has also been found to affect sexual activity. Patients with psoriasis, particularly women, have difficulty in starting sexual relationships. However, sexual problems have not been correlated with the extent of the skin disease or with its location in the genital area.<sup>11-13</sup>

Psoriasis is often associated with psychiatric problems, such as depression and anxiety,<sup>14</sup> that also have a negative effect on quality of life (QoL).<sup>15,16</sup> Patients with psoriasis attribute a significant negative effect on their QoL to their disease and/or its treatment. The classical treatments of psoriasis are often unsatisfactory for patients in being inconvenient, messy, and associated with side effects.<sup>17-19</sup>

The World Health Organization Quality of Life Group defined QoL as "an individual's perception of their position in life in the context of the culture and

value system in which they live and in relation to their goals, expectations, standards, and concerns".<sup>20</sup> This definition has deeply changed the concept of health, which is no longer considered to be the absence of illness but rather a state of suitable physical, psychological, and social wellbeing. Testa and Simonson,<sup>21</sup> beginning from the definition proposed by the World Health Organization, defined health-related QoL as "the aspects (or domains) of the physical-functional, psychological-emotional, and social health that are influenced by the experiences, beliefs, objectives, and expectations of the individuals".

The aim of this study was to investigate the QoL and clinical characteristics of patients with psoriasis referred to the dermatological clinic of the University of Rome Tor Vergata as candidates to receive one of the new biological treatments, in order to better manage the disease and the effect of treatment while also considering the patient's point of view.

## PATIENTS AND METHODS

### Patients

Consecutive patients with psoriasis who were referred to a dermatological reference centre as candidates for biological treatments were invited to participate in the study. To be eligible for treatment with a biological drug, patients had to demonstrate unresponsiveness to other systemic therapies, including methotrexate, cyclosporine, and psoralen ultraviolet A. Socio-demographic variables and clinical data were collected for each patient, with the clinical severity of psoriasis evaluated using the Psoriasis Area and Severity Index (PASI).

### Quality of Life Measurements

Three different measures were used to assess QoL: the Dermatology Life Quality Index (DLQI), the Skindex-29, and the Psoriasis Disability Index (PDI).

### Dermatology Life Quality Index

The DLQI is the first dermatology-specific QoL questionnaire. Published in 1994, the questionnaire was designed to be used in adults over the age of 18 years, and consists of 10 questions concerning symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment; all questions relate to the previous week. Each question is scored from 0–3 and the total score can range from 0–30, with higher scores

indicating greater disability. The DLQI has been shown to have good reliability and validity when used in a dermatological setting.<sup>22</sup>

### Skindex-29

Skindex-29 is a reliable and valid instrument that has been specifically designed for measuring QoL in dermatological patients. Twenty-nine items are combined to form three scales assessing essential domains of QoL (burden of symptoms, social functioning, and emotional state). Patients are requested to answer the questions, referring to the previous 4-week period, using a 5-point scale ranging from 'Never' to 'All the time'. The scores from the three scales, and an overall or summary score, are calculated on a 100-point scale, with lower scores indicating a better QoL.<sup>23</sup>

### Psoriasis Disability Index

The PDI is an appropriate method to give a rapid global measure of psoriasis disability. It considers the impact of psoriasis on daily activities, work, personal relationships, leisure, and treatment-related aspects. The questionnaire includes 15 questions that refer to the previous 4-week period, and which are answered using a 4-point linear scale ranging from 0 (no disability) to 3 (maximum level of disability).<sup>24</sup>

### Statistical Analysis

Data were entered into a computerised database and QoL scores were calculated for each QoL measure. All statistical analyses were performed using STATA 11.2 software (Statacorp LP Inc., College Station, Texas, USA).

## RESULTS

### Patient Characteristics

One hundred and eighty patients (104 males and 76 females) aged between 20 and 79 years, and affected by moderate-to-severe psoriasis were recruited to the study. At baseline, the mean PASI was 16.65 (range: 8–59) and the mean disease duration was 22.9 years (range: 5–65). A majority of the patients (80%) were refractory to at least two conventional therapies, and only 20% of patients showing comorbidities (i.e. hypertension, hyperlipidaemia, cardiovascular disease) were treated with only one conventional therapy.

**Table 1: Mean quality of life scores in 180 psoriasis patients starting a biological treatment.**

Patient characteristic	n (%)	DLQI	PDI	Skindex-29			
				Symptoms	Emotions	Functioning	
Sex	Male	104 (58)	11.5	25.9	47.2	49.1	38.2
	Female	76 (42)	12.8	28.8	47.0	53.5	36.7
Age, years	<40	46 (31)	12.0	25.3*	43.5	46.5*	33.6
	40–49	42 (28)	13.3	33.1*	52.1	58.4*	43.7
	>50	62 (41)	11.0	24.0*	46.5	48.4*	36.6
PASI	<10	54 (36)	9.5*	20.3*	37.8*	42.9*	31.2*
	10–19.9	61 (41)	12.2*	27.8*	49.8*	52.8*	38.5*
	>20	35 (23)	15.2*	35.0*	57.3*	55.4*	43.1*
Disease duration, years	<10	55 (37)	12.8	27.8	47.8	51.5	36.2
	>10	95 (63)	11.6	26.6	47.0	50.2	38.4

\*p<0.05.

DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index; PDI: Psoriasis Disability Index.

## Quality of Life

According to all of the scales that we utilised, mean QoL scores were invariably high, indicating a severe burden of disease (Table 1). The only statistically significant difference was observed in relation to PASI scores, with higher DLQI scores in higher PASI categories. Females had a mean score slightly higher than males, patients aged 40–49 years had slightly higher scores than younger and older patients, and patients with a shorter duration of disease had slightly higher scores than those with a longer disease history. Unsurprisingly given its high correlation with the DLQI,<sup>25</sup> the PDI scores showed exactly the same pattern.

For the different variables considered, the pattern of mean scores obtained using Skindex-29 was fairly consistent with those observed using the DLQI and the PDI, with only a few non-significant exceptions. However, patients with a longer duration of disease were slightly more affected on the ‘Functioning’ scale than those with a shorter duration. The observed differences were statistically significant for PASI on all three Skindex-29 scales, as well as for age on the ‘Emotions’ scale, with higher scores in the 40–49 years age group.

To estimate the independent role of sex, age, duration of disease, and PASI on the two

dermatology-specific instruments (DLQI and Skindex-29), while simultaneously adjusting for all of the other variables, we created separate logistic regression models. The dependent variables were defined using a cut-off value of 10 for the DLQI, and cut-off values of 50, 50, and 33 for the ‘Symptoms’, ‘Emotions’, and ‘Functioning’ scales of the Skindex-29, respectively.<sup>26</sup> For DLQI, only PASI >20 was associated with scores >10, with an odds ratio (OR) of 6.3 versus PASI <10 (95% confidence interval [CI]: 2.1–19.4).

For the Skindex-29 ‘Symptoms’ scale, in addition to PASI >20 (OR: 7.4, 95% CI: 2.5–22.4), age was associated with significant differences both for the 40–49 years (OR: 3.4, 95% CI: 1.2–9.2) and the >50 years (OR: 3.5, 95% CI: 1.4–8.9) age groups versus patients in the <40 years age group. For ‘Functioning’, significant ORs were observed for the 40–49 years age group (OR: 3.1, 95% CI: 1.2–8.2) and the >50 years age group (OR: 2.6, 95% CI: 1.1–6.3) versus the <40 years age group; and PASI >20 was significantly higher than PASI <10 (OR: 3.7, 95% CI: 1.3–10.3). Interestingly, for the ‘Emotions’ scale, in addition to the difference between the 40–49 years and <40 years age groups (OR: 3.2, 95% CI: 1.2–8.5), a statistically significant difference was observed for women versus men (OR: 2.5, 95% CI: 1.1–5.4).

## DISCUSSION

In this study we describe the QoL of a group of psoriasis patients selected for biological treatments, and show that the level of QoL impairment was extremely high, according to both dermatological instruments and questionnaires. Given that these treatments will be increasingly used in patients with psoriasis over the next few years, it is important to investigate the impact of the disease on QoL in order to better evaluate a patient's condition at the start of treatment and to monitor the course of the disease in relation to the effects of the therapy, both during the period of administration and after the end of treatment cycles.

A novelty of our study is that QoL was evaluated using different instruments. The use of dermatology-specific QoL questionnaires, such as the DLQI and the Skindex-29, can highlight specific problems due to skin involvement, while allowing comparisons with a wide range of dermatological conditions. Furthermore, disease-specific instruments, such as the PDI, are appropriate tools to explore disability due specifically to psoriasis. We observed that QoL, as measured by the different instruments, was fairly consistently associated with gender (women had a worse QoL than men), age (patients in the intermediate age group [i.e. 40–49 years] had a worse QoL), and clinical severity.

In our study we observed that women had a worse QoL than men. Gender differences with regard to the impact of psoriasis are an important issue to consider. Recent studies in several diseases have shown that women report more physical disability, a lower QoL, more pain, more symptoms, and more

psychological problems compared with men.<sup>27-29</sup> Several studies have shown women to be more likely than men to report impairment of psoriasis-related QoL.<sup>30,31</sup> In our study, women had higher scores on the vast majority of scales used. This is almost certainly due to the cosmetic disfigurement caused by psoriasis, as recent studies have shown that women are more invested in their appearance and tend to be dissatisfied with their body-image.<sup>32</sup>

Multivariate analyses showed that the variables more associated with QoL were high PASI scores (in DLQI and the 'Symptoms' scale of Skindex-29) and the 40–49 years age group (for all Skindex-29 scales). Our results show that older patients with psoriasis had worse QoL: patients who were >40 years old had significantly lower mean QoL improvement than younger patients ( $\leq 40$  years of age). It is important to note that no association between PASI and the psycho-social measures used in this study (e.g. 'Symptoms' and 'Functioning' scales of the Skindex-29) was observed.

In conclusion, our results show how pervasive the impact of psoriasis is in patients who are starting a biological treatment, and they further confirm the lack of a strong correlation between measures of clinical severity and QoL. Our findings stress the complexity of the factors that affect QoL in patients with moderate-to-severe psoriasis, and underline the need for a thorough assessment of QoL in these patients. If the primary success of healthcare for patients suffering from psoriasis is to maximise functioning in everyday life and achieve the highest possible level of QoL, then it will be difficult to show that these objectives are achieved if we fail to collect valid measurements that document the true extent of the changes induced by dermatological interventions.

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