Dermatology Practical & Conceptual

CORONATE: A Novel Questionnaire to Assess the Long-Term Impact of Psoriasis on Patients' Lives

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ABSTRACT

Introduction: Psoriasis has a profound impact on patients' quality of life, affecting their emotional well-being, social interactions, and career choices. However, current assessment tools fail to capture the long-term burden of psoriasis.

Objective: The aim of this study was to develop the CORONATE questionnaire, designed to assess the lifelong impact of moderate-to-severe psoriasis on patients' lives.

Methods: A multicenter cross-sectional study was conducted in 15 Italian dermatology centers. This study included 300 patients (age ≥30 years) diagnosed with moderate-to-severe psoriasis (PASI ≥10 or PASI <10 with involvement of sensitive areas). The CORONATE questionnaire, initially consisting of 25 items, was refined through factor analysis. Exploratory and confirmatory factor analyses were performed.

Results: The final questionnaire included 18 items grouped into two dimensions: "Work Issues" (5 items) and "Psychosocial Life" (13 items). Factor analysis confirmed strong internal consistency (Cronbach's alpha: Work Issues = 0.81; Psychosocial Life = 0.91). The model showed excellent fit indices (χ^2 (153) = 6956.471, $P<0.001$; Comparative Fit Index = 0.998; Tucker-Lewis Index = 0.998; Standardized Root Mean Square Residual = 0.053).

Conclusion: The CORONATE questionnaire is a reliable tool for assessing the cumulative burden of psoriasis. Its implementation in clinical practice may improve personalized patient care.

Introduction

The burden of psoriasis is substantial, significantly affecting the physical, psychological, and socioeconomic dimensions of patients' lives. Long-term, uncontrolled psoriasis can progressively limit opportunities, influencing major life-changing decisions (e.g., having a child, getting married or divorced, choosing a job), and ultimately hindering life potential [1,2]. As noted by Augustin et al., the Cumulative Life Course Impairment (CLCI) is influenced by multiple factors, including disease severity, chronicity, early onset, stigmatization, and lack of social support, among others. Particularly relevant are the aesthetic impact, symptoms, and extent of the disease, which play a significant role in shaping the cumulative burden on patients' lives.

In recent years, there has been a growing emphasis on research and health promotion interventions that employ life course approaches, aligning with the strategic objectives outlined by the World Health Organization and the Sustainable Development Goals set forth by the United Nations for 2030 [3,4]. To date, studies examining the global burden of psoriasis have predominantly focused on assessing the quality of life, capturing the impact of the condition at specific points in patients' lives. These studies, which are often cross-sectional and primarily retrospective, struggle to capture the progressive nature of the impairment that accumulates in psoriasis patients over their lifetimes. CLCI aims to address this limitation by seeking to explore the ongoing impact of psoriasis on patients' lives over time [5,6]. However, the assessment of CLCI poses significant challenges due to its inherent patient-specific and multifaceted nature. In 2013, Sampogna [6] suggested a list of items representing the aspects potentially influenced by the disease during the life course concerning education and work, personal relationships, social life, negative coping, and emotional impact.

Recently, two questionnaires that may be used in patients with chronic skin conditions have been proposed by Braren-von Stülpnagel et al. [7]: the DermCLCI-r and the DermCLCI-p. The DermCLCI-r investigates the aspects that the patient has found burdensome over the course of the disease, thus assessing retrospective CLCI, while the second explores the aspects that the patient found burdensome in the previous two weeks, with the aim of assessing current CLCI and future risk. However, at present, the two sets of items have not been analyzed for item reduction, and they have not been validated. No validated tool exists for effectively measuring CLCI, and ongoing discussion persists regarding the selection of variables to be included in such assessments.

Objectives

This study was specifically designed as two separate phases. The present study focuses on the first phase aiming to develop a new psychometric index, the CORONATE questionnaire, designed to assess the long-term impact of moderate-to-severe psoriasis on patients' life. A second phase, confirmatory analysis in an independent sample, is currently ongoing to specifically validate the CORONATE questionnaire.

Materials and Methods

Patients and Study Design

This was a multicenter observational cross-sectional study conducted between January and September 2023 to evaluate the long-term impact of moderate-to-severe psoriasis on patients' life. The CORONATE Study included two phases, the first involving an exploratory development of the questionnaire in order to refine items and identify a preliminary factor structure (present study), and the second, performed on an independent sample, designed to validate the CORONATE questionnaire. The study involved 15 dermatology centers across Italy, ensuring a balanced geographical distribution. Eligible participants were male and female patients aged 30 years or older diagnosed with moderate-to-severe plaque psoriasis (PASI ≥ 10 or PASI < 10 with sensitive areas involvement) at least 10 years prior to enrollment. Patients were required to understand and complete the study-related questionnaire, and no restriction was imposed regarding ongoing psoriasis therapies. The study protocol was approved by the local ethics committees of all participating centers, and informed consent was obtained from all participants.

Data Collection

Data collection included sociodemographic characteristics such as sex, age, height, weight, education, marital status, and employment. Clinical data on psoriasis localization, disease duration, current treatment, comorbidities, smoking habits, and alcohol consumption were also recorded. Psoriasis severity was assessed using the Psoriasis Area Severity Index (PASI) and the Physician Global Assessment (PGA) on a 5-point scale ranging from clear to severe. Itch intensity was measured on a visual analogue scale (VAS) from 0 (no itch) to 10 (worst imaginable itch). Quality of life related to dermatology was assessed using the Dermatology Life Quality Index (DLQI), which consists of 10 items scored from 0 to 3, with higher scores indicating greater impairment [8].

CORONATE Questionnaire

The CORONATE questionnaire, comprising 25 items, was designed to explore the impact of psoriasis on various life domains, including education, work, personal relationships, social activities, sports, clothing choices, time lost due to treatment, addictions, and emotional well-being. The questionnaire was constructed based on expert consensus and a review of key aspects affecting patients' quality of life, including psychosocial, emotional, and functional dimensions. A preliminary phase involved the identification of 26 questions through collaboration between an epidemiologist and dermatologists from the main Italian dermatological clinics. These questions were refined in 2022 by a group of 13 experienced dermatologists using a simplified consensus procedure, which led to the removal of one item. This resulted in a draft questionnaire with 25 items, which was subsequently used in the present study. Patients completed the questionnaire electronically during a single visit using a tablet device, which ensured that all items were answered. Responses were recorded on a 4-point Likert scale (false, almost false, almost true, true).

Statistical Analysis

As this was an exploratory study, no formal sample size calculation was required. A total of 300 patients were included to facilitate item reduction and factor analysis. Categorical variables are described using frequencies and percentages, while quantitative variables are reported as mean and standard deviation. Exploratory factor analysis (EFA) was conducted on the 25 items using the unweighted least squares (ULS) method with Oblimin oblique rotation to extract factors. Items with factor loadings below 0.40 were excluded. A confirmatory factor analysis (CFA) was subsequently performed on the remaining items to validate the factor structure. The model fit was assessed using several indices: the chi-square (χ^2) test, with p-values >0.05 indicating an acceptable fit (noting its sensitivity to sample size); the Comparative Fit Index (CFI), where values ≥0.95 indicate good fit and values ≥0.90 are acceptable; the Tucker-Lewis Index (TLI), with thresholds similar to CFI; the standardized root mean square residual (SRMR), where values <0.08 indicate good fit [9].

Statistical analyses were performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA) and Factor 12.04.04 for Windows.

Results

Patient Characteristics

The characteristics of the study population are summarized in Table 1. Data were collected from 300 patients, 66.3% of whom were male. The mean age was 54.9 years (standard deviation, SD: 11.9), the mean PASI was 5.0 (SD: 7.9), and the mean DLQI was 4.3 (SD: 6.5). The most frequent psoriasis localizations at diagnosis were the upper extremities, lower extremities, scalp, and trunk. At the time of the survey, 232 patients (79.7%) were being treated with biologics, 30 (10.3%) with non-biological systemic treatments, and 29 (10%) with topical treatments.

Factor Analysis and Model Refinement

Factor analysis results are detailed in Table 2. An exploratory factor analysis (EFA) conducted on the 25 items identified a two-factor model as the best fit for the data [$\chi^2(300) = 7786.273$, $P<0.001$; CFI=0.997; TLI=0.997; SRMR=0.055]. Items with factor loadings below 0.40 (items 1, 2, 11, 18, 19, 20, and 21) were removed, leaving 18 items in the final model. The revised model demonstrated excellent fit indices: $\chi^2(153) = 6956.471$, $P<0.001$; CFI=0.998; TLI=0.998; SRMR=0.053.

Identified Dimensions and Scale Reliability

The analysis revealed two distinct dimensions, representing different domains of life course impairment. The first dimension, labeled "Work Issues," included five items (items 3, 4, 5, 6, and 7) addressing the impact of psoriasis on professional life, such as the inability to work, influence on job choice, loss of workdays, job loss, and reduced earnings. The second dimension, labeled "Psychosocial Life," comprised 13 items exploring the broader psychosocial impacts of psoriasis. These included relationships with partners and others, sexual life, limitations in family and social activities, participation in sports, time spent on treatments, travel limitations, clothing choices, feelings of sadness and introversion, and general influence on life.

Table 2 reports the factor loadings for each item, clearly delineating their distribution across the two dimensions. Internal consistency was satisfactory for both subscales, with Cronbach's alpha values of 0.81 for the Work Issues dimension and 0.91 for the Psychosocial Life dimension. Consequently, the final CORONATE questionnaire was reduced to 18 items, as shown in Table 3.

Discussion

In this study, we developed the CORONATE questionnaire to assess the multifaceted impact of psoriasis on patients' life. The final tool consisted of 18 items, of which five specifically addressed work-related issues and the other 13, psychosocial aspects.

The five items belonging to this scale explored topics such as the impact of psoriasis on the ability to work, how the condition influenced job selection, the number of workdays missed or experiences of job loss attributable to the condition, and any changes in earnings associated with psoriasis. A study utilizing the National Psoriasis Foundation database revealed that individuals with severe psoriasis were more likely to have a low income (defined as < US$30,000) compared to those with mild psoriasis ($P<0.001$) [10]. Moreover, patients with psoriasis often face challenges in securing or maintaining employment due to decreased productivity and the need to allocate time for treatments during

Table 1. Description of the study population of 300 patients with psoriasis.

Variable	Level	N (%)	
Sex	*Male*	199 (66.3)	
	Female	101(33.7)	
Education	*Primary*	8 (2.7)	
	Secondary	103 (34.3)	
	High school	114 (38.0)	
	University	75 (25.0)	
Marital status	*Single*	68 (22.7)	
	With partner	224 (74.6)	
	Widow/er	8 (2.7)	
Employment	*Employed*	205 (68.4)	
	Looking for a job	3 (1.0)	
	Unemployed	28 (9.3)	
	Without employment by choice	3 (1.0)	
	Retired	61 (20.3)	
		Mean±SD	
Age		54.9±11.9	
Time since diagnosis (years) *		17.0 (19.0-21.4)	
BMI		26.8±4.7	
Current PASI		5.0±7.9	
VAS itch		2.5±3.2	
		At diagnosis* N (%)	Current N (%)
Localization	*Scalp*	215 (71.7)	71 (23.7)
	Face	84 (28.0)	30 (10.0)
	Trunk	207 (69.0)	78 (26.0)
	Arms	256 (85.3)	114 (38.0)
	Legs	247 (82.3)	111 (37.0)
	Nails	115 (38.3)	64 (21.3)
	Hands	132 (44.0)	73 (24.3)
	Feet	105 (35.0)	54 (18.0)
	Folds	61 (20.3)	29 (9.7)
	Genitals	96 (32.0)	38 (12.7)
Smoking	*Yes*	110 (36.7)	
	Ex	141 (47.0)	
Alcohol	*Yes*	214 (71.3)	
PGA	*Clear*	132 (44.0)	
	Almost clear	69 (23.0)	
	Mild	31 (10.3)	
	Moderate	50 (16.7)	
	Severe	18 (6.0)	
Currently treated	*Biologic*	232 (79.7)	
	Non-biologic systemic	30 (10.3)	
	Topic	29 (10)	
DLQI		4.3±6.5	

* Diagnosis of moderate-to-severe psoriasis. Abbreviations: BMI: body mass index; DLQI: Dermatology Life Quality Index; PASI: Psoriasis Area and Severity Index; PGA: Physician Global Assessment; VAS: visual analogue scale.

Table 2. Factor loadings of the items of the CORONATE questionnaire from exploratory factor analysis (EFA) and confirmatory factor analysis (CFA). Factor 1 represents work-related aspects, while Factor 2 represents psychosocial aspects of life impairment.

Items of the CORONATE questionnaire	EFA		CFA	
	Factor 1	Factor 2	Factor 1	Factor 2
1. I have not studied what I would have liked to because of my psoriasis.				
2. I lost years at school or at university because of my psoriasis.				
3. For a time in my life, I was unable to work because of my psoriasis.		0.767		0.799
4. I could not embrace the profession I would have liked to because of my psoriasis.		0.528		0.540
5. I have lost many days of work because of my psoriasis.		0.670		0.692
6. I happened to lose my job because of my psoriasis.		0.605		0.592
7. I have earned less money than I might have earned because of my psoriasis.		0.750		0.731
8. I have experienced relationship problems because of my psoriasis.	0.652		0.654	
9. I had difficulties in finding a partner because of my psoriasis.	0.585		0.566	
10. I have experienced problems in my sex life because of my psoriasis.	0.658		0.635	
11. I did not have any children because of my psoriasis.				
12. I have caused limitations in my family life because of my psoriasis.	0.670		0.661	
13. I have had to withdraw from many social activities because of my psoriasis.	0.618		0.621	
14. I have not practiced as much sport as I would have liked to because of my psoriasis.	0.595		0.597	
15. I have lost a lot of time in my life because of treatment and management of my psoriasis.	0.514		0.519	
16. I have travelled less than I would have liked to because of my psoriasis.	0.551		0.554	
17. I could not wear clothing or shoes I liked because of my psoriasis.	0.620		0.626	
18. I have been (or am still) under psychiatric/psychological treatment because of my psoriasis.				
19. I have often drunk a lot of alcohol because of my psoriasis.				
20. I have been (or am still) smoking too much because of my psoriasis.				
21. I have been (or am still) addicted to drugs because of my psoriasis.				
22. I think psoriasis has made me sadder than I could have been.	0.815		0.819	
23. I think psoriasis has made me less extroverted than I could have been.	0.827		0.831	
24. I think psoriasis has made me less confident about the future than I could have been.	0.774		0.776	
25. All things considered, my life has taken a worse direction because of my psoriasis.	0.603		0.617	

Loadings lower than absolute 0.300 are omitted.

flare-ups [11]. A Polish study found that 23% of patients reported that psoriasis negatively influenced their choice of career, with an unemployment rate of 14.3%, exceeding the national average of 11.9% in Poland [12]. However, the causal relationship between psoriasis and the subsequent reduction in social and financial well-being remains uncertain. Published studies, primarily utilizing cross-sectional designs, lack the ability to establish causality regarding the effects of psoriasis on income and employment status. Indeed, the financial difficulties experienced by patients may worsen psoriasis severity due to increased stress, alcohol consumption, smoking and reduced treatment adherence. Alternatively, the severity of psoriasis and the associated costs and time required for treatment may directly impact work performance, subsequently affecting income levels. Therefore, further investigation is needed to unravel the direction of causality in this relationship.

Only one cohort study has investigated this topic in a prospective manner, revealing a slight decrease in income among patients with psoriasis, with variations observed over

Table 3. The CORONATE questionnaire.

	False	Almost false	Almost true	True
1. For a time in my life, I was unable to work because of my psoriasis.				
2. I could not embrace the profession I would have liked to because of my psoriasis.				
3. I have lost many days of work because of my psoriasis.				
4. I happened to lose my job because of my psoriasis.				
5. I have earned less money than I might have earned because of my psoriasis.				
6. I have experienced relationship problems because of my psoriasis.				
7. I had difficulties in finding a partner because of my psoriasis.				
8. I have experienced problems in my sex life because of my psoriasis.				
9. I have caused limitations in my family life because of my psoriasis.				
10. I have had to withdraw from many social activities because of my psoriasis.				
11. I have not practiced as much sport as I would have liked to because of my psoriasis.				
12. I have lost a lot of time in my life because of treatment and management of my psoriasis.				
13. I have travelled less than I would have liked to because of my psoriasis.				
14. I could not wear clothing or shoes I liked because of my psoriasis.				
15. I think psoriasis has made me sadder than I could have been.				
16. I think psoriasis has made me less extroverted than I could have been.				
17. I think psoriasis has made me less confident about the future than I could have been.				
18. All things considered, my life has taken a worse direction because of my psoriasis.				

Questions 1–5: Work/productivity subscale ; Questions 6–18: Psychosocial subscale.

time [13]. Additionally, the proportion of employed individuals decreased among patients with psoriasis compared to controls following the onset of the condition, with a 10% reduction in employment among patients with psoriasis [13]. These findings suggest that the impact of psoriasis on professional careers may contribute to lower incomes and diminished socioeconomic well-being.

The questionnaire also delved into the psychosocial aspects of life, encompassing 13 items that explored various dimensions such as relationships with partners and others, sexual activity, impacts on family and social life, engagement in sports, time allocation for treatment, travel limitations, clothing choices, feelings of sadness, introversion tendencies, and overall life influence.

Recent studies showed that 80–90% of patients reported some degree of psoriasis-related discrimination and stigmatization, which had negative effects on their personal life [14,15]. Up to 20% of patients with psoriasis have been banned from hair salons, swimming pools, gyms or SPA [16]. Over time, these reiterated episodes may concur to cause poor self-confidence, low social connection, and failure to achieve full life potential. In fact, in order to prevent uncomfortable situations due to stigmatization of the disease, patients with psoriasis elaborate strategies to avoid social interaction in public occasions [17]. Often, this attitude becomes so invasive that it leads patients to limiting not only social exposure but also the chance to create and solidify intimate relations [18].

Study Limitations

This study has several limitations. First, the CORONATE questionnaire was developed through expert consensus among dermatologists rather than being derived directly from patient experience. While this approach was pragmatic for an exploratory study, best practice in developing patient-reported outcome tools is to generate items from qualitative research with patients, ensuring their lived experiences are accurately represented.

Second, the questionnaire was not pretested with psoriasis patients for clarity, comprehensibility, or ease of completion, which limits certainty about its applicability in routine clinical practice.

Third, in the CORONATE, the factor analysis excluded the items concerning education and addictions. The items that were not included in the final version of the questionnaire were deemed statistically unhelpful in explaining the variance of the initial data. Although these items may be conceptually related, they did not demonstrate psychometric relevance and were thus removed. Their inclusion resulted in poor fit of the questionnaire adaptation, failing to sufficiently explain the original data variance.

Fourth, like other retrospective tools, CORONATE is susceptible to recall bias. However, since patient-centered measures aim to explore the subjective experiences and perspectives of patients, one can argue that their perceptions of the disease's impact on their life course indeed reflect the "truth". Nevertheless, it is plausible that some patients may unintentionally deny or fail to recognize the adverse effects of psoriasis on their life decisions. This coping strategy, known as denial or repression, may lead patients to ignore the presence of a stressor in an attempt to minimize its effect [19].

Fifth, the cross-sectional design restricts conclusions about causality and does not capture changes over time. In addition, factor analysis excluded items concerning education and addictions. Although these domains may be conceptually related to the cumulative impact of psoriasis, they did not demonstrate psychometric relevance and were therefore removed, as their inclusion resulted in poor model fit and insufficient explanatory power.

We sought to mitigate some of these limitations through rigorous psychometric testing, including item reduction and factor analysis, which demonstrated strong internal consistency and validity. Nevertheless, future research should incorporate qualitative interviews with psoriasis patients, cognitive debriefing to test clarity, and longitudinal validation to strengthen the patient-centered nature of the instrument and confirm its ability to capture long-term life course impairment.

Conclusions

The CORONATE questionnaire has the potential to effectively capture the main aspects of the impact of psoriasis on patients. Compared to the recently proposed DermCLCI-r questionnaire, both tools retrospectively assess how the disease has affected the course of life, focusing on life choices and emotional impact. However, the DermCLCI-r has not undergone an item reduction procedure, and neither tool has been validated. Additionally, while the DermCLCI-r is designed for use in multiple chronic skin conditions, including atopic dermatitis and hidradenitis suppurativa, the CORONATE questionnaire is specifically tailored to psoriasis. The advantage is that while it would be possible to compare the results in many chronic skin diseases, it is possible that some aspects are specific to a disease and not applicable to others.

The use of these kinds of tools could be helpful not only to identify and understand patients' vulnerability to the impact of psoriasis and address risk factors at an early stage but also to tailor treatment to the individual and foster improved treatment adherence. A prompt control of the disease in patients with moderate-to-severe psoriasis may plausibly prevent CLCI. Future longitudinal research is needed to validate these findings and further explore the impact of such tools. In the second phase of the CORONATE Study, the CORONATE questionnaire is currently undergoing psychometric validation in a new cohort involving 250 patients with moderate-to-severe psoriasis. Additional studies are also planned to formally validate the CORONATE questionnaire, extending its application to different patient populations affected by psoriasis.

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