Responsiveness of the Colombian Spanish version of the DLQI in patients with psoriasis who started treatment with biologic therapy

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Dedicatory

To our lifetime partners for their patience and unconditional support and to Horus, Isis, Mara, and Porfirio for their tranquility and constant presence.

Acknowledgements

We are grateful to Medicarte SA and EPS Sura for granting access to their coded patient database. We also thank the epidemiologists Catalina Orozco and Carolina Hincapié, the physicians Caren Ton, Alejandro Berbeo and Sebastián Burgos for their collaboration, and the Group of Investigative Dermatology (GRID) for co-funding and supporting the logistics of the project.

Resumen

Antecedentes: La psoriasis es una enfermedad crónica que no solo se ha relacionado con pérdida de productividad laboral y ausentismo, sino también con discapacidad, depresión e ideación suicida en los pacientes afectados. El objetivo de este estudio fue evaluar la sensibilidad al cambio del instrumento DLQI en su versión en español colombiano en pacientes con psoriasis que inician tratamiento con terapia biológica.

Métodos: estudio observacional, descriptivo de corte transversal basado en datos retrospectivos de pacientes con psoriasis atendidos en un centro de referencia en la ciudad de Medellín. Se recolectaron variables clínicas y sociodemográficas, así como de calidad de vida de los pacientes. Se aplicó la escala DLQI antes y 3 meses después de iniciar la terapia biológica. Para valorar el cambio entre la medición basal y las mediciones posteriores, se determinó el tamaño del efecto con la prueba “d” de Cohen.

Resultados: Se incluyeron 257 pacientes. Su edad media fue de 52.8 años. Los principales subtipos de psoriasis fueron la psoriasis en placas (88.3%), la artropatía psoriásica (33,5%). Los subtipos con mayores puntajes de DLQI promedio basal fueron la psoriasis pustulosa (14.2), psoriasis en cuero cabelludo (6.81) y la psoriasis palmoplantar (5.71). La mayoría de los pacientes evaluados recibieron tratamiento con medicamentos anti-factor de necrosis tumoral. Tanto el DLQI como el PASI tuvieron menores puntuaciones promedios a lo largo del seguimiento. El tamaño del efecto obtenido por la prueba de Cohen, entre la medición basal vs el primer seguimiento del DLQI luego de iniciada la terapia biológica fue leve en el caso de las psoriasis clasificadas como leves al inicio, sin embargo, el tamaño del efecto fue fuerte para pacientes que tuvieron psoriasis grave en su evaluación inicial.

Conclusiones: La versión en Español Colombiano del Índice de Calidad de Vida Dermatológica (DLQI) en pacientes con psoriasis tiene una sensibilidad baja a pesar de que la terapia instaurada en estos pacientes si fue eficaz.

Palabras claves: psoriasis; artritis psoriásica; calidad de vida; terapia biológica; sensibilidad al cambio

Abstract

Background: Psoriasis is a chronic disease that has been associated not only with loss of work productivity and absenteeism, but also with disability, depression, and suicidal ideation in affected patients. The aim of this study was to evaluate the responsiveness of the Colombian Spanish version of DLQI instrument in patients with psoriasis who initiate treatment with biologic therapy.

Methodology: Observational, descriptive, cross-sectional study based on retrospective data of patients with psoriasis treated in a referral center in the city of Medellin. Clinical and sociodemographic variables were collected, as well as patients' quality of life. The DLQI scale was applied before and 3 months after initiating biologic therapy. To assess the change between baseline and subsequent measurements, the effect size was determined with Cohen's d-test.

Results: A total of 257 patients were included. Their mean age was 52.8 years. The main subtypes of psoriasis were chronic plaque psoriasis (88.3%), psoriatic arthropathy (33.5%). The subtypes with the highest baseline mean DLQI scores were pustular psoriasis (14.2), scalp psoriasis (6.81) and palmoplantar psoriasis (5.71). Most of the patients evaluated received treatment with anti-tumor necrosis factor drugs. Both the DLQI and PASI had lower mean scores throughout follow-up. The effect size obtained by Cohen's d-test, between baseline vs. first follow-up DLQI measurement after initiation of biologic therapy was mild for psoriasis classified as mild at baseline; however, the effect size was strong for patients who had severe psoriasis at their initial evaluation.

Conclusions: The Colombian Spanish version of the Dermatological Quality of Life Index (DLQI) in patients with psoriasis has a low responsiveness even though the therapy implemented in these patients was effective.

Key words: Psoriasis; Arthritis Psoriatic; Quality of Life; Biological Therapy; Responsiveness

Introduction

Psoriasis is a systemic and chronic, immune-mediated disease with a significant negative physical and psychosocial impact. Estimated prevalence's of the disease among adults in the United States and South America are 3% and 1%, respectively[1,2]. Like other chronic diseases, psoriasis not only causes an important economic and clinical burden, but it also causes major limitations in daily living and in health-related quality of life (HRQoL)., even in mild forms, also causing stigmatization, low self-esteem, depression, anxiety, suicidal ideation[3]. Furthermore, it has been reported that psoriasis can affect mental and physical functioning comparable to that seen in diabetes, cancer, and hypertension[4]. Thus, at present, therapeutic objectives in psoriasis require, on the one hand, the quantification of the severity of skin symptoms and, on the other hand, the assessment of HRQoL[5]. Such information is relevant not only for patient follow-up but also for making decisions in clinical practice, and for planning and designing public health strategies.

To date, different tools have been used to measure the severity of psoriasis. For instance, in 2003, Naldi et al[6] identified more than 40 clinical assessment instruments published between 1977 and 2000, and in 2010 Bronsard et al found 21 questionnaires for the assessment of quality of life published between 1988 and 2009[7]. Among all those reported, the Psoriasis Area and Severity Index (PASI) used for clinical assessment, and the Dermatology Life Quality Index (DLQI) for quality-of-life assessment, are the most referenced and used tools because of their proven reliability, applicability, and reproducibility[8–10].

The DLQI is a unidimensional scale consisting of a short, simple, and easily self-administered questionnaire composed of 10 questions, which is answered in less than 5 minutes[11]. Its questions relate to the perceived impact of skin disease on quality of life in the past week, and it has been used in dermatologic patients over 16 years of age. DLQI questions cover aspects such as symptoms and feelings (questions 1 and 2), daily activities (questions 3 and 4), leisure activities (questions 5 and 6), work and school life (question 7), interpersonal relationships (questions 8 and 9) and side effects of treatment (question 10)[11]. Each item has four response possibilities according to the Likert scale: 0, not at all/not relevant; 1, a little; 2: a lot; 3: very much. This scale scoring is calculated by adding the scores

of each question, resulting in a minimum of 0 and a maximum of 30, and high scores are related to worsening quality of life[11].

The DLQI is one of the most widely used instruments and in fact it is the HRQoL scale that in the last 2 decades has served as a reference to evaluate the efficacy of any therapeutic alternative for psoriasis and particularly to define the need or not for the initiation of biologic therapy[5,12]. Indeed, in several European countries where the drug reimbursement strategy is used, the DLQI together with the PASI correspond to the two main criteria used for defining the indication of high-cost therapies in psoriasis[13–15].

The responsiveness of the DLQI has been evaluated in various countries such as the United States, England, Spain, Denmark, Germany, Belgium, and Brazil, among others[16–19], but little is known about it in Spanish-speaking Latin American countries. This is relevant and deserves to be studied, because if the response capacity of a quality-of-life instrument is not satisfactory, this could cast doubt on its validity.

Regarding the severity of the disease, the PASI was created in 1978 for a more objective monitoring of psoriasis under treatment with acitretin and corresponds to a standardized score designed to assess clinical severity and to monitor response to treatment in plaque psoriasis[20]. This scale considers not only the severity of lesions, but also the percentage of body surface area affected to achieve a score between 0 and 72, the higher the score, the greater the severity of psoriasis.

Although psoriasis severity would be expected to align with scores on HRQoL scales, the correlation found between these tools has been variable[10,21–27] . Some studies have found a strong correlation between PASI and DLQI[28–32] but others such a recent systematic review that included 2291 DLQI measurements found a moderate relationship (r=0.556) between PASI and DLQI averages, moreover, when discriminating patients with DLQI >10, this correlation weakened (r=0.302)[33]. Another study that evaluated the correlation between DLQI and PASI found a value of r=0.33, and the variables that explained more than 60% of the variance in the DLQI questionnaires were illness-related stress, depression, and severity[34]. In addition, a study in Brazil also found a nonlinear correlation between the PASI and the DLQI[10], which could be explained by a non-equivalence of some items of the instrument between the original version and the translated version, as suggested by Nijsten et al[35]. Other

studies have found that besides the PASI, personal aspects such as: the patient's perception of the cause of the disease; the expectation of cure instead of symptom control; and the time spent living with the skin condition, have a very important impact on quality of life[27–29,36].

Considering the relevance of the DLQI in clinical decision-making and that there may be variability in its performance due to issues specific to each country, it is necessary to assess whether the Colombian Spanish version of the DLQI sensitively detects clinical changes in patients undergoing a high-cost therapy such as biological therapy.

6 Methodology

Study design

This was an observational, study with a longitudinal design (with at least two measurements) based on retrospective data gathered from medical records.

Population

Patients seen between 2014 and 2022 at Medicarte IPS in Medellin, a specialized outpatient center and advanced pharmacotherapeutic management. Colombian patients older than 16 years with a clinical diagnosis of psoriasis or psoriatic arthropathy identified by the following International Classification of Diseases (ICD) version 10 codes, were included: L400 psoriasis vulgaris, L401 generalized pustular psoriasis, L404 guttate psoriasis, L405 arthropathic psoriasis, L408 other psoriasis, and L409 unspecified psoriasis. Patients without a clinical history, and those patients without at least two DLQI and PASI measurements were excluded.

Information sources

The information was obtained from a database that included coded information that prevented patient identification.

Study variables

Sociodemographic variables such as age, sex, educational level, socioeconomic status, and clinical variables such as the subtype of psoriasis and the severity of the disease measured by PASI were all assessed. Mild, moderate, and severe involvement corresponded to a PASI score <5, ≥5-10, and severe ≥10, respectively[13]. In addition, information about comorbidities were collected. Also, data regarding previous treatments, the type of biologic

used. Initial PASI/DLQI and at intervals of approximately 3 months were gathered. The interpretation of the DLQI was based on the rule of ten.

Statistical analysis

Quantitative variables: mean or median and standard deviation or interquartile range (25th percentile to 75th percentile) according to the assumption of distribution (Shapiro Wilk test).

Categorical variables: frequency and percentage. These characteristics are presented according to gender and subtype of psoriasis.

Responsiveness was assessed by calculating Glass' delta and Cohen's d, between patients 'first measurement and each further DLQI measurements with values <0.20 reflecting no change, between 0.20 to 0.50 slight change, between 0.50 to 0.80 moderate change and greater than 0.80 reflecting an important or large change[37,38]. Responsiveness was explored according to psoriasis subtype, and baseline disease severity assessed by PASI (mild: <5; moderate: ≥5-9.9 and severe: ≥10). Results were presented with their respective 95% confidence interval. All analyses were performed in the R software/language version 4.1.1[39] with the packages *effectsize*[40] (calculation of Cohen's d and Glass delta); *ggplot2* and *ggstatsplot* (spaghetti plot) to represent the change between one measurement and another)[41,42], *janitor*, *lubridate* and *dplyr* (data manipulation)[43–45].

Ethical considerations

The present study was carried out in accordance with the Declaration of Helsinki. All patients included in the study signed an informed consent form. This study was approved by the bioethics committee of the School of Medicine of the University of Antioquia and the ethical committees of Medicarte and Sura EPS.

7 Results

Of the total of 704 potentially eligible patients only 652 had a confirmed diagnosis of psoriasis, and among these, only 257 patients had an initial DLQI and PASI measurement and at least a second measurement of DLQI **Figure** 1**.**

Figure *1***.** Flow chart of participant recruitment and follow-up.

Note: DLQI= Dermatology Life Quality Index, PASI: Psoriasis area and severity index

Participants mean age was 52.8 years (SD:14.4), the median age at diagnosis was 32. years [22.0, 45.0], and 21.5% had a family history of psoriasis. The demographic characteristics and baseline clinical features are summarized in **Table** 1. On the other hand, the characteristics of the excluded population are in **Table** 7.

Table *1***.** Sociodemographic characteristics

Characteristics	Female (N= 108)	Male (N= 149)	Total (N= 257)
Mean age (SD)	51.0 (16.0)	54.1 (12.9)	52.8 (14.4)
Education level (%)			
Primary	27 (25.0%)	37 (24.8%)	64 (24.9%)
Secondary	40 (37.0%)	48 (32.2%)	88 (34.2%)
Technical technological	10 (9.3%)	29 (19.5%)	39 (15.2%)
Undergraduate Posgraduate	20 (18.5%)	31 (20.8%)	51 (19.8%)
No Data/Not Applicable	11 (10.2%)	4 (2.7%)	15 (5.8%)
Socioecononomic status			
1	4 (3.7%)	9 (6.0%)	13 (5.1%)
2	26 (24.1%)	38 (25.5%)	64 (24.9%)
3	74 (68.5%)	90 (60.4%)	164 (63.8%)

4	3 (2.8%)	10 (6.7%)	13 (5.1%)
5	1 (0.9%)	2 (1.3%)	3 (1.2%)
Marital Status			
Married/unmarried union	49 (45.4%)	117 (78.5%)	166 (64.6%)
Single	47 (43.5%)	26 (17.4%)	73 (28.4%)
Divorced	5 (4.6%)	4 (2.7%)	9 (3.5%)
Widowed	7 (6.5%)	2 (1.3%)	9 (3.5%)
Median age at diagnosis [IR]	31.0 [18.8, 45.0]	33.0 [24.0, 46.0]	32.0 [22.0, 45.0]
PASI			
Mild	74 (68.5%)	96 (64.4%)	170 (66.1%)
Moderate	15 (13.9%)	29 (19.5%)	44 (17.1%)
Severe	19 (17.6%)	24 (16.1%)	43 (16.7%)
Psoriasis subtypes			
Chronic plaque	93 (86.1%)	134 (89.9%)	227(88.3%)
Arthropathy	50 (46.3%)	36 (24.2%)	86 (33.5%)
Ungular	15 (13.9%)	27 (18.1%)	42 (16.3%)
Scalp	14 (13.0%)	17 (11.4%)	31 (12.1%)
Palmoplantar	4 (3.7%)	3 (2.0%)	7 (2.7%)
Pustular	4 (3.7%)	1 (0.7%)	5 (1.9%)
Guttate	3 (2.8%)	2 (1.3%)	5 (1.9%)
Inverse	0 (0%)	2 (1.3%)	2 (0.8%)
Erithrodermic	1 (0.9%)	1 (0.7%)	2 (0.8%)

Note: Abreviations: SD, Standard Deviation; IR: Interquartile Range (25th percentile – 75th percentile)

The main subtype of psoriasis was plaque presentation (88.3%) (**Table** 1 and 2s). The most frequent comorbidities corresponded to overweight (43.1%), high blood pressure (27.6%), obesity (22.9%), smoking (14.4%), heart disease (14%) and diabetes (12.5%) (**Table** 2).

Table *2***.** Comorbidities presented by the included patients**.**

Comorbidity	Female (N= 108)	Male (N= 149)	Total (N= 257)
Sedentarism	64 (59.3%)	95 (63.8%)	159 (61.9%)
Overweight	45 (41.6%)	66 (44.2%)	111 (43.1%)
Latent tuberculosis	33 (30.6%)	58 (38.9%)	91 (35.4%)
High blood pressure	25 (26.6%)	39 (29.1%)	64 (27.6%)
Obesity	18 (16.9%)	41 (27.5%)	59 (22.9%)

Family History of Psoriasis	21 (19.4%)	35 (23.5%)	56 (21.8%)
Tabaquism	13 (12.0%)	24 (16.1%)	37 (14.4%)
Cardiac disease	13 (12.0%)	23 (15.4%)	36 (14.0%)
Diabetes mellitus	10 (9.3%)	22 (14.8%)	32 (12.5%)
Rheumatologic disease	13 (12.0%)	16 (10.7%)	29 (11.3%)
Dislipidemia	5 (4.6%)	21 (14.1%)	26 (10.1%)
Psiquiatric disease	8 (7.4%)	10 (6.7%)	18 (7.0%)
Fatty liver	2 (1.9%)	8 (5.4%)	10 (3.9%)
Active treated tuberculosis	4 (3.7%)	5 (3.4%)	9 (3.5%)
COPD	2 (1.9%)	4 (2.7%)	6 (2.3%)
Depresion	3 (2.8%)	2 (1.3%)	5 (1.9%)
Alcoholism	1 (0.9%)	4 (2.7%)	5 (1.9%)
Obstructive Sleep Apnea	2 (1.9%)	1 (0.7%)	3 (1.2%)
Migrane	2 (1.9%)	0 (0%)	2 (0.8%)
Systemic cáncer personal history	0 (0%)	2 (1.4%)	2 (0.8%)
Prediabetes	1 (0.9%)	1 (0.7%)	2 (0.8%)
HIV	0	0	0

Note: Abbreviations: COPD: Chronic obstructive pulmonary disease; HIV: Human Immunodeficiency Virus

About half of the patients had had some previous topical treatment while almost 40% had received phototherapy at some point (**Table** 3).

In relation to the type of biologic received, more than half of the patients received a tumor necrosis factor (TNF) inhibitor (57.8%), with adalimumab as the most used biologic in almost all plaque psoriasis and in guttate psoriasis, etanercept and ixekizumab were the most used in palmoplantar forms, whereas secukinumab and ustekinumab were mostly used in inverse psoriasis (**Table** 3 and).

Table *3***.** Treatments received by included patients.

Type of treatment	Female	Male	Total
Current biologic therapy	98 (90.7%)	142 (95.3%)	240 (93.4%)
Adalimumab	18 (16.7%)	45 (30.2%)	63 (24.5%)

Etanercept	25 (23.1%)	35 (23.5%)	60 (23.3%)
Ustekinumab	16 (14.8%)	29 (19.5%)	45 (17.5%)
Secukinumab	18 (16.7%)	18 (12.1%)	36 (14.0%)
Ixekizumab	9 (8.3%)	8 (5.4%)	17 (6.6%)
Golimumab	4 (3.7%)	1 (0.7%)	5 (1.9%)
Infliximab	2 (1.9%)	3 (2.0%)	5 (1.9%)
Guselkumab	2 (1.9%)	3 (2.0%)	5 (1.9%)
Certolizumab	3 (2.8%)	0 (0%)	3 (1.2%)
Rizankizumab	1 (0.9%)	0 (0%)	1 (0.4%)
Previous systemic or biologic therapy	60 (55.6%)	97 (65.1%)	157 (61.1%)
Previous topic treatment	45 (41.7%)	82 (55.0%)	127 (49.4%)
Previous Phototherapy	30 (27.8%)	67 (45.0%)	97 (37.7%)
Current systemic treatment	0 (9.3%)	7 (4.7%)	17 (6.6%)

The mean of initial PASI was 5.58 (SD 8.79) and the means of the subsequent measurements were 2.64, 2.46 and 2.19, reflecting a decrease in severity. On the other hand, the mean initial DLQI was 5.33 (SD 6.75), a value that, as in the case of PASI, decreased in subsequent measurements (3.10, 2.46, 2.14) (**Table** 4). Among the different subtypes of psoriasis, the greatest impairment in quality of life was found in pustular psoriasis (value of 14.2 (SD 13.1), followed by patients with scalp and plantar palmar involvement (**Table** 9).

Table *4***.** PASI and DLQI scores on different measurements.

	Female	**Male**	**Total**
Initial PASI	**N=108**	**N=149**	**N=257**
Mean (SD)	5.30 (8.06)	5.79 (9.30)	5.58 (8.79)
Median [IR]	1.70 [0, 7.33]	2.40 [0.400, 8.00]	2.00 [0.100, 7.80]
PASI 2	**N= 93**	**N=134**	**N=227**
Mean (SD)	2.15 (4.82)	2.98 (5.52)	2.64 (5.25)
Median [IR]	0.200 [0, 2.40]	0.600 [0, 3.20]	0.500 [0, 2.70]
PASI 3	**N=73**	**N=102**	**N=175**

Mean (SD)	2.28 (6.08)	2.59 (5.97)	2.46 (6.00)
Median [IR]	0.200 [0, 1.20]	0.800 [0, 2.20]	0.400 [0, 1.90]
PASI 4	**N= 60**	**N= 79**	**N= 139**
Mean (SD)	1.98 (6.06)	2.34 (4.48)	2.19 (5.20)
Median [IR]	0.100 [0, 1.60]	0.500 [0, 2.95]	0.400 [0, 2.10]
PASI 5	**N= 48**	**N= 56**	**N= 104**
Mean (SD)	3.36 (9.94)	2.43 (5.14)	2.86 (7.71)
Median [IR]	0.400 [0, 1.80]	0.400 [0, 1.60]	0.400 [0, 1.73]
PASI 6	**N= 31**	**N= 34**	**N= 65**
Mean (SD)	4.75 (9.40)	2.23 (2.97)	3.43 (6.90)
Median [IR]	0.800 [0, 4.45]	1.20 [0, 3.50]	0.800 [0, 4.00]
Initial DLQI	**N=108**	**N=149**	**N=257**
Mean (SD)	5.82 (6.89)	4.68 (6.54)	5.15 (6.70)
Median [IR]	3.50 [1.00, 8.00]	1.00 [0, 7.75]	2.00 [0, 8.00]
DLQI 1	**N= 94**	**N= 134**	**N= 228**
Mean (SD)	3.90 (5.81)	2.52 (5.25)	3.10 (5.53)
Median [IR]	1.00 [0, 5.00]	0 [0, 2.00]	1.00 [0, 3.00]
DLQI 2	**N=69**	**N=104**	**N=173**
Mean (SD)	3.32 (5.96)	1.89 (4.07)	2.46 (4.94)
Median [IR]	1.00 [0, 3.00]	0 [0, 2.00]	0 [0, 2.00]
DLQI 3	**N=55**	**N=78**	**N=133**
Mean (SD)	2.49 (3.80)	1.88 (4.30)	2.14 (4.10)
Median [IR]	1.00 [0, 2.00]	0 [0, 2.00]	0 [0, 2.00]
DLQI 4	**N=38**	**N=63**	**N=101**
Mean (SD)	2.79 (5.18)	1.87 (4.31)	2.22 (4.65)
Median [IR]	0.500 [0, 2.75]	0 [0, 2.00]	0 [0, 2.00]

Note: Abbreviations: SD: Standard Deviation; DLQI: Dermatology Life Quality Index; PASI: Psoriasis area and Severity Index; IR: Interquartile Range (25^{th} percentile – 75^{th} percentile)

When evaluating the responsiveness of DLQI without considering the initial severity of psoriasis (initial measurement vs. first further measurement) a Cohen's d of =0.37 (95% CI [0.24-0.50] was found (**Table** 5 and **Figure** 2A) and for the

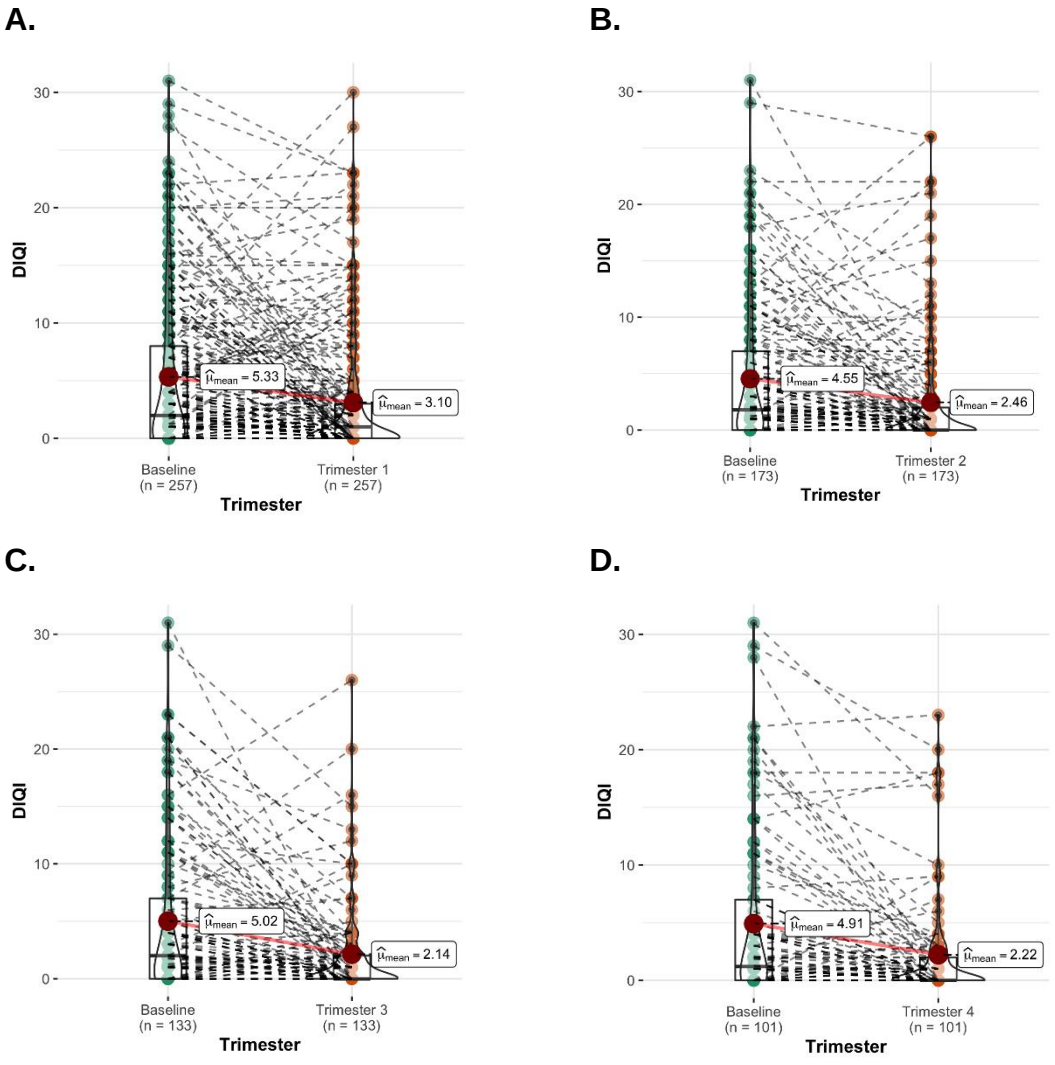
second, third and last measurements values were 0. 38 95% CI [0.22- 0.53], 0.45 CI [0.28, 0.63], 0.46 CI [0.26, 0.67] respectively, with a significant *p* value in all measurements (**Table** 5**Table** 5**Table** 5**.** and **Figure** 2). As for Glass' delta, the values in those measurements were 0.40 95% CI [0.21- 0.60] (**Table** 5 and **Figure** 2), 0.42 95% CI [0.18- 0.67], 0.70 95% CI [0.36, 1.05] and 0.58 95% CI [0.21, 0.95], respectively (**Table** 5 and **Figure** 2).

Table *5***.** Measuring responsiveness with the DLQI.

Responsiveness in the first quarter				
DLQI	**Initial (N=257)**	**Quarter 1 (N=257)**	**Cohen's d/ IC95%****	**Glass' Delta/ IC95%**
Mean (SD)	5.33 (6.75)	3.10 (5.53)	0.37 [0.24, 0.50]	0.40 [0.21, 0.60]
Median [IR]	2.00 [0, 8.00]	1.00 [0, 3.00]		
Responsiveness in the second quarter				
DLQI	**Initial (N=173)**	**Quarter 2 (N=173)**	**Cohen's d/ IC95%****	**Glass' Delta/ IC95%**
Mean (SD)	4.55 (6.29)	2.46 (4.94)	0.38 [0.22, 0.53]	0.42 [0.18, 0.67]
Median [IR]	1.80 [0, 7.00]	0 [0, 2.00]		
Responsiveness in the third quarter				
DLQI	**Initial (N=133)**	**Quarter 3 (N=133)**	**Cohen's d/ IC95%****	**Glass' Delta/ IC95%**
Mean (SD)	5.02 (6.93)	2.14 (4.10)	0.45 [0.28, 0.63]	0.70 [0.36, 1.05]
Median [IR]	2.00 [0, 7.00]	0 [0, 2.00]		
Responsiveness in the fourth quarter				
DLQI	**Initial (N=101)**	**Quarter 4 (N=101)**	**Cohen's d/ IC95%****	**Glass' Delta/ IC95%**
Mean (SD)	4.91 (7.34)	2.22 (4.65)	0.46 [0.26, 0.67]	0.58 [0.21, 0.95]
Median [IR]	1.20 [0, 7.00]	0 [0, 2.00]		

Note: Abbreviations: SD: Standard Deviation; IR: Interquartile Range intercuartil (25th percentile-75th percentile)

Figure *2*. Spaghetti plot with the distribution of baseline DLQI according to DLQI in the different trimesters.



Note: A. First trimester. B. Second trimester. C. Third trimester. D. Fourth trimester. Abbreviations: DLQI, Dermatology Life Quality Index.

Depending on psoriasis severity according to PASI, it was found that the responsiveness in DLQI increased as higher levels of clinical severity were found,

with Cohen's d of 0.25 [0.10, 0.41], 0.43 [0.12, 0.74] and 0.68 [0.34, 1.02] in mild, moderate, and severe forms, respectively (**Table** 6).

Table *6***.** Responsiveness according to psoriasis severity.

Mild Psoriasis PASI <5				
First Quarter				
DLQI	**Initial (N=170)**	**Quarter 1 (N=170)**	**Cohen's d/ IC95%****	**Glass' Delta/ IC95%**
Mean (SD)	2.94 (4.70)	1.84 (3.79)	0.25 [0.10, 0.41]	0.29 [0.05, 0.53]
Median [IR]	1.00 [0, 4.00]	0 [0, 2.00]		
Second quarter				
DLQI	**Initial (N=121)**	**Quarter 2 (N=121)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	2.61 (4.43)	1.45 (3.17)	0.29 [0.10, 0.47	0.29 [0.10, 0.47
Median [IR]	1.00 [0, 4.00]	0 [0, 1.00]		
Third quarter				
DLQI	**Initial (N=95)**	**Quarter 3 (N=95)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	2.77 (4.66)	1.66 (3.75)	0.24 [0.03, 0.44]	0.30 [-0.03, 0.62]
Median [IR]	1.00 [0, 4.00]	0 [0, 1.00]		
Forth quarter				
DLQI	**Initial (N=74)**	**Quarter 4 (N=74)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	2.95 (5.61)	1.15 (2.67)	0.32 [0.08, 0.55]	0.68 [0.13, 1.21]
Median [IR]	1.00 [0, 3.75]	0 [0, 1.00]		
Moderate Psoriasis PASI ≥5-10				
First Quarter				
DLQI	**Initial (N=44)**	**Quarter 1 (N=44)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	7.49 (5.78)	4.77 (6.30)	0.43 [0.12, 0.74]	0.43 [0.02, 0.84]
Median [IR]	6.50 [1.98, 12.3]	2.00 [0, 6.25]		
Second Quarter				

DLQI	Initial (N=31)	Quarter 2 (N=31)	Cohen's d/ IC95%**	Glass' Delta/IC95%
Mean (SD)	7.15 (5.53)	3.45 (5.63)	0.78 [0.28, 1.31]	1.07 [0.29, 1.82]
Median [IR]	5.00 [1.95, 11.5]	1.00 [0, 4.50]		
Third Quarter				
DLQI	**Initial (N=20)**	**Quarter 3 (N=20)**	**Cohen's d/ IC95%****	**Glass'Delta/ IC95%**
Mean (SD)	7.74 (5.63)	2.75 (4.67)	0.24 [0.03, 0.44]	0.30 [-0.03, 0.62]
Median [IR]	8.00 [2.73, 12.5]	2.00 [0, 3.00]		
Forth quarter				
DLQI	**Initial (N=16)**	**Quarter 4 (N=16)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	7.17 (6.14)	2.88 (4.80)	0.80 [0.23, 1.40]	0.89 [0.03, 1.74]
Median [IR]	5.50 [1.60, 12.5]	1.00 [0, 3.00]		
Severe Psoriasis PASI ≥10				
First Quarter				
DLQI	**Initial (N=42)**	**Quarter 1 (N=42)**	**Cohen's d/ IC95%****	**Glass's Delta/IC95%**
Mean (SD)	12.1 (8.14)	5.98 (7.87)	0.68 [0.34, 1.02]	0.78 [0.31, 1.25]
Median [IR]	11.0 [6.00, 18.0]	2.00 [0, 9.75]		
Second Quarter				
DLQI	**Initial (N=20)**	**Quarter 2 (N=20)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	10.9 (8.48)	7.05 (8.80)	0.51 [0.04, 1.00]	0.44 [-018, 1.06]
Median [IR]	9.5 [3.00, 18.3]	3.00 [0, 13.5]		
Third Quarter				
DLQI	**Initial (N=17)**	**Quarter 3 (N=17)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	12.8 (9.21)	4.18 (4.84)	1.26 [0.63, 1.95]	1.79 [0.57, 2.96]
Median [IR]	15.0 [3.00, 19.0]	2.00 [0, 4.00]		
Forth Quarter				
DLQI	**Initial (N=10)**	**Quarter 4 (N=10)**	**Cohen's d/ IC95%****	**Glass' Delta/IC95%**
Mean (SD)	13.2 (9.34)	7.70 (8.96)	0.96 [0.20, 1.80]	-0.34 [0.34, 1.54]
Median [IR]	14.00 [4.75, 18.8]	3.50 [2.00, 14.8]		

Note: Abbreviations: SD: Standard Deviation; DLQI: Dermatology Life Quality Index; PASI: Psoriasis area and severity index; IR: Interquartile Range (25^{th} percentile- 75^{th} percentile)

8 Discussion

Considering the relevance of the impact of psoriasis on quality of life in patients with psoriasis, we investigated the responsiveness of the Colombian Spanish version of the Dermatologic Quality of Life Index (DLQI), which is the quality-of-life questionnaire most used in clinical trials and in daily practice for clinical decision making. The main finding of this study was that the Colombian Spanish version of the DLQI has a moderate responsiveness in patients with psoriasis, even though a highly effective therapy was administered. This contrasts with other studies in which the instrument has been shown to be highly sensitive to change in the course of the disease after initiating therapy[16,46]. This finding is not unusual, as more publications calling for a review of the instrument for the so-called "not relevant response (NRR)" in patients with psoriasis have been emerging[47–49]. In contrast, the DLQI was specifically found to be more sensitive to change in patients with severe psoriasis, a finding that is consistent with the greater specificity of the instrument in severe inflammatory dermatoses.

The population evaluated showed a slight predominance of the male gender, with a median age at diagnosis of 32 years, and with chronic plaque psoriasis as the most prevalent subtype, findings that are comparable to what has already been reported[50–53]. Family history of psoriasis was recorded in 21.8% of the participants, a relevant finding considering the importance of genetics in the development of psoriasis[54], and the higher percentages of family history of psoriasis reported in other studies[55]. The median initial PASI in the population studied reflects a moderate severity of the disease, one of the main reasons to prescribe high efficacy therapies as biologics[56]. Among these, anti-TNFs use prevailed which could be partly explained due to less missing information from patients collected during the first years of the study, timing in which these types of biologicals were the only commercially available in Colombia. To avoid selection bias, the clinical and sociodemographic data of the excluded population were analyzed, and no difference were found between those populations.

Interestingly, sedentary lifestyle, overweight/obesity, hypertension, and diabetes mellitus were the most frequent comorbidities found, what emphasizes the knowledge that psoriasis is a systemic inflammatory disease[57,58]. Importantly more than one third of the patients had a diagnosis of latent tuberculosis a finding that highlights the need to treat patients before the initiation of any biologic to prevent the risk of TB reactivation[59].

About the effect on HRQoL, our study found a initial DLQI score of 5.33, which contrasts with what has been reported in other cultures[16,60] indicating a moderate effect on quality of life, which may be due to the shortcomings of the instrument in our culture. These findings are reinforced by the fact that many of the questions of the instrument are influenced by factors other than the disease (age, gender, nationality) and by others inherent to the scale such as psychological impairment[48].

In addition, in this study, the subtypes related with the greatest compromise of HRQoL of life were the pustular form, followed by the scalp, palmoplantar and the ungular psoriasis. The latter finding is relevant as nail psoriasis affects 80-90% of patients with psoriasis, with pain described in up to 52% of cases, in addition to limitations in their daily life, domestic activities and professional activity[61].

Regarding psoriatic arthropathy, DLQI scored in the range of a mild involvement, a result that was not surprising given that the scale focuses on skin symptoms and there are few questions on daily functioning. However, this contrasts with other studies that have shown a worse quality of life in patients with joint involvement[62]. These findings must be interpreted with caution as the poor performance of the instrument in these scenarios, its lack of sensitivity to detect symptoms other than those of the skin, the lack of questions on pain or functionality, may all lead to an underestimation of the severity of the disease and might bias the decision of starting biological therapy.

The low DLQI and PASI scores compared to other reports in the literature could be explained because a large percentage of our population had previously received biological (46.6%) and systemic (79.3%) therapy. In addition, as mentioned above, there are clinical variants that are not adequately evaluated by

these questionnaires (palmoplantar, scalp, pustular, psoriatic arthritis) and some comorbidities, social and insurance causes which dictate the prescription making process.

During follow-up, there was an overall decrease in PASI y DLQI, an expected change in patients undergoing biologic therapy[56,63] as patients were expected to have a better HRQoL after treatment with biologic therapy [64–66]. However, it should be noted that PASI in the third and fourth trimester remained stable. This finding is consistent with other studies which show that not all patients report a DLQI of 0 despite a complete clearing of lesions, as other features such as the concern of relapsing or treatment issues (i.e.: adverse effects, costs, travel) may influence instrument scoring[32]. At this point it is striking to emphasize one of our findings, the responsiveness of the instrument increases in severe psoriasis according to their initial PASI, but it decreases ostensibly in patients with milder clinical status. This lack of responsiveness of the scale should be considered when assessing lack of improvement, lack of response or worsening, as well as the patient's perception of therapeutic response, to help dictate dermatologists' decisions[29,67].

Another study that included multiple dermatologic diseases with a significant representation of psoriasis (50% of the cases evaluated) found an overall responsiveness of the DLQI of 0.3; a value that coincides with our findings. In contrast to our analyses, these authors analyzed each item of the instrument individually, and found a similar individual effect among the questions except for those concerning relationships, sex life and treatment effects where the sensitivity value was lower. In addition, one of their most important conclusions is that to achieve a clinically significant, a change in at least 4 different response category items is required[18], a difference that may be more difficult to achieve if we remember the non-relevant response mentioned above.

It is noteworthy that comparison of DLQI has shown that the latest has better sensitivity than PASI and PGA. This study divided the response to 12 weeks of treatment of the patients in 3 groups. The "responders (PASI ≥ 75%)" group, showed a difference of 12.17 points in the DLQI against the baseline DLQI, while

the group of "non-responders (<PASI 50%)" showed a difference of 1.77 points. They also reported a greater responsiveness for the DLQI during their follow-up.

It is noteworthy that comparison of DLQI has shown that the latest has better sensitivity than PASI and PGA. This superiority is supported in studies that when comparing these 3 instruments in subgroups of "responders (PASI ≥ 75%)", found differences of 12.17 points in the DLQI with respect to baseline and in a group of "non-responders (<PASI 50%)", the change was only 1.77 points after 12 weeks of therapy with evidence of greater responsiveness for the DLQI during this follow-up[46]. These findings complement our results: baseline severity improves the responsiveness of the DLQI.

The main strengths of the study rely on its target on patients belonging to the largest cohort of patients with psoriasis on biologic therapy in Colombia and the evaluation of the responsiveness of the DLQI in patients with mild, moderate, and severe psoriasis as this DLQI psychometric property has been poorly studied as has been demonstrated in a systematic review, in which such analysis was reported in just 1.1% of included articles[68].

The main limitation of this study was its retrospective design, which is more prone to information bias, which explains missing data in a significant number of patients, in addition to the COVID-19 pandemic during years 2020 and 2021, a fact that limited in-person follow-ups. To the lack of information consigned in the charts, we have to point out the lack of knowledge in respect to patient's adherence and the uncertainty that our healthcare system may addition to our results [69,70].

9 Conclusions

This study showed a lack of responsiveness, of the non-validated Colombian Spanish version of the DLQI when evaluating patients with mild psoriasis. So, results of this version against the original one cannot be compared. Given the importance of HRQoL for decision making in clinical practice (particularly in the initiation or change of a high-cost therapy such as a biological) and for government policy proposals, it is important to have a valid and reliable scale, therefore, the cross-cultural adaptation and validation of the DLQI for Colombia is needed to obtain a version with measurement properties more like the original instrument.

10 Recommendation

Further studies should considerate a prospective analysis which guarantee complete data before and after the intervention, and the opportunity to analyze the scales' properties against an anchor (i.e., PASI or Skindex-29). Finally, a multivariate analysis could provide more information about the true influence of each item of the scale and other factors that may influence the DLQI's responsiveness.

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Supplementary

Table *7.* Sociodemographic characteristics of excluded populations

Characteristics	Female (N= 224)	Male (N= 170)	Total (N= 394)
Mean age (SD)	52.1 (15.6)	50.5 (14.0)	51.4 (14.9)
Education level (%)			
Primary	33 (14.7%)	24 (14.1%)	57 (14.5%)
Secondary	74 (33.0%)	57 (33.5%)	131 (33.2%)
Technical/technological	29 (12.9%)	20 (11.8%)	49 (12.4%)
Undergraduate Posgraduate	50 (22.53%)	50 (29.4%)	100 (25.4%)
Socioecononomic status			
1	17 (7.6%)	12 (7.1%)	29 (7.4%)
2	43 (19.2%)	41 (24.1%)	84 (21.3%)
3	137 (61.2%)	99 (58.2%)	236 (59.9%)
4	23 (10.3%)	9 (5.3%)	32 (8.1%)
5	3 (1.3%)	4 (2.4%)	7 (1.8%)
6	1 (0.4%)	5 (2.9%)	6 (1.5%)
Marital Status			
Married/unmarried union	116 (51.8%)	115 (67.6%)	231 (58.6%)
Single	80 (35.7%)	43 (25.3%)	123 (31.2%)
Divorced	17 (7.6%)	10 (5.9%)	27 (6.9%)
Widowed	11 (4.9%)	2 (1.2%)	13 (3.3%)
Median age at diagnosis [IR]	36.0 [20.8, 50.0]	33.5 [21.0, 45.0]	35.0 [21.0, 47.0]
PASI			
Mild	98 (43.8%)	59 (34.7%)	157 (39.8%)
Moderate	35 (15.6%)	30 (17.6%)	65 (16.5%)
Severe	15 (6.7%)	44 (25.9%)	59 (15.0%)
Psoriasis subtypes			
Chronic plaque	197 (87.9%)	151 (88.8%)	348 (88.3%)
Arthropathy	50 (46.3%)	36 (24.2%)	86 (33.5%)
Ungular	15 (13.9%)	27 (18.1%)	42 (16.3%)
Scalp	14 (13.0%)	17 (11.4%)	31 (12.1%)

Palmoplantar	4 (3.7%)	3 (2.0%)	7 (2.7%)
Inverse	7 (3.1%)	3 (1.8%)	10 (2.5%)
Guttate	4 (1.8%)	4 (2.4%)	8 (2.0%)
Pustular	4 (3.7%)	1 (0.7%)	5 (1.9%)
Erithrodermic	0	0	0
Comorbilities			
Sedentarism	137 (61.2%)	96 (56.5%)	233 (59.1%)
Overweight	45 (41.6%)	66 (44.2%)	111 (43.1%)
Latent tuberculosis	33 (30.6%)	58 (38.9%)	91 (35.4%)
High blood pressure	63 (28.1%)	52 (30.6%)	115 (29.2%)
Obesity	18 (16.9%)	41 (27.5%)	59 (22.9%)
Family History of Psoriasis	44 (19.6%)	35 (20.6%)	79 (20.1%)
Rheumatologic disease	34 (15.2%)	22 (12.9%)	56 (14.2%)
Cardiac disease	13 (12.0%)	23 (15.4%)	36 (14.0%)
Tabaquism	24 (10.7%)	18 (10.6%)	42 (10.7%)
Diabetes mellitus	17 (7.6%)	23 (13.5%)	40 (10.2%)
Dislipidemia	18 (8.0%)	22 (12.9%)	40 (10.2%)
Psiquiatric disease	12 (5.4%)	4 (2.4%)	16 (4.1%)
Active treated tuberculosis	4 (3.7%)	5 (3.4%)	9 (3.5%)
Alcoholism	5 (2.2%)	7 (4.1%)	12 (3.0%)
Fatty liver	3 (1.3%)	7 (4.1%)	10 (2.5%)
Migrane	7 (3.1%)	1 (0.6%)	8 (2.0%)
Depresion	3 (2.8%)	2 (1.3%)	5 (1.9%)
COPD	2 (0.9%)	4 (2.4%)	6 (1.5%)
Prediabetes	5 (2.2%)	0 (0%)	5 (1.3%)
Obstructive Sleep Apnea	4 (1.8%)	1 (0.6%)	5 (1.3%)
Systemic cancer personal history	1 (0.4%)	3 (1.8%)	4 (1.0%)
HIV	0 (0%)	1 (0.6%)	1 (0.3%)

Table 8. Population characteristics according to psoriasis type.

Variable	Chronic plaque (N=227)	Psoriatic arthropathy (N=86)	Nail (N=42)	Scalp (N=31)	Palmo plantar (N=7)	Pustular (N=5)	Guttate (N=5)	Inverse (N=2)	Erythroderm (N=2)
Mean age (SD)	52.7 (14.6)	53.2 (14.3)	48.1 (11.5)	40.2 (10.3)	60.4 (15.6)	54.2 (17.8)	57.2 (12.4)	51.5 (13.4)	52.0 (4.24)
Diagnosis age in years Median [QI]	31.0 [22.0, 43.5]	38.0 [24.0, 49.5]	34.0 [27.0, 43.8]	26.0 [19.5, 32.0]	48.0 [39.5, 52.0]	53.0 [33.0, 55.0]	35.0 [32.0, 56.0]	29.5 [24.8, 34.3]	28.5 [26.3, 30.8]
Previous topic therapy	112 (49.3%	24 (27.9%)	21 (50.0%)	20 (64.5%)	6 (85.7%)	3 (60.0%)	4 (80.0%)	2 (100%)	2 (100%)
Previous phototherapy	88 (38.8%)	11 (12.8%)	13 (31.0%)	18 (58.1%)	3 (42.9%)	2 (40.0%)	4 (80.0%)	1 (50.0%)	2 (100%)
Previous systemic drug or biologic	140 (61.7%)	49 (57.0%)	24 (57.1%)	24 (77.4%)	6 (85.7%)	3 (60.0%)	4 (80.0%)	0 (0%)	2 (100%)
Current systemic drug	15 (6.6%)	12 (14.0%	3 (7.1%)	1 (3.2%)	0 (0%)	2 (40.0%)	0 (0%)	0 (0%)	0 (0%)
Current biologic									
Adalimumab	57 (25.1%)	19 (22.1%)	11 (26.2%)	8 (25.8%)	1 (14.3%)	0 (0%)	3 (60.0%)	0 (0%)	0 (0%)
Etanercept	54 (23.8%)	19 (22.1%)	5 (11.9%)	5 (16.1%)	2 (28.6%)	0 (0%)	1 (20.0%)	0 (0%)	1 (50.0%)
Ustekinumab	41 (18.1%)	5 (5.8%)	6 (14.3%	6 (19.4%)	1 (14.3%)	0 (0%)	0 (0%)	1 (50.0%)	0 (0%)
Secukinumab	30 (13.2%)	17 (19.8%)	8 (19.0%)	5 (16.1%)	1 (14.3%)	1 (20.0%)	0 (0%)	1 (50.0%)	0 (0%)
Ixekizumab	13 (5.7%)	5 (5.8%)	4 (9.5%)	3 (9.7%)	2 (28.6%)	1 (20.0%)	0 (0%)	0 (0%)	0 (0%)
Guselkumab	4 (1.8%)	0 (0%)	0 (0%)	1 (3.2%)	0 (0%)	0 (0%)	1 (20.0%)	0 (0%)	0 (0%)
Golimumab	4 (2.0%)	4 (4.7%)	2 (4.8%)	0 (0%)	0 (0%)	1 (20.0%)	0 (0%)	0 (0%)	1 (50.0%)
Infliximab	5 (2.5%)	3 (3.5%)	2 (4.8%	1 (3.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Certolizumab	3 (1.5%)	2 (2.3%)	1 (2.4%)	1 (3.2%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Table *9*. Characterization of clinimetry and responsiveness according to psoriasis type.

Variable	Chronic Plaques (N= 227)	Psoriatic arthropathy (N= 86)	Nail (N= 42)	Scalp (N= 31)	Palmo plantar** (N= 7)	Guttate** (N= 5)	Pustular** (N=3)
Mean initial DLQI (SD)	5.51 (6.90)	4.66 (6.19)	5.20 (7.02)	6.81 (6.87)	5.71 (8.56)	5.20 (5.93)	12.3 (15.)
Mean DLQI 2 (SD)	3.11 (5.46)	3.38 (5.39)	2.79 (5.37)	5.06 (7.34)	1.29 (1.38)	6.00 (11.8)	16 (14.0)
Mean both DLQI (SD)	4.31 (6.33)	4.02 (5.82)	3.99 (6.33)	5.94 (7.11)	3.50 (6.32)	5.60 (8.80)	14.2(13.1)
Median DLQI (QI)	2.10 [0, 9.00]	3.00 [0, 6.75]	2.00 [0, 9.00]	4.00 [1.00, 13.0]	1.00 [0.500, 7.50]	4.00 [0, 8.00]	8.00 [4.00, 18.5]
Median DLQI 2 (QI)	0 [0, 3.00]	1.00 [0, 4.75]	0 [0, 2.75]	1.00 [0, 8.50]	1.00 [0.500, 1.50]	1.00 [0, 2.00]	22.0 [11.0, 24.0]
Median both DLQI (QI)	1.00 [0, 6.00]	2.00 [0, 5.00]	1.00 [0, 5.00]	2.00 [0.250, 11.8]	1.00 [0.250, 3.50]	1.50 [0, 7.00]	15.0 [2.00, 25.0]
Glass´s Delta IC 95%	0.44 [0.23, 0.65]	0.24 [-0.09, 0.56]	0.45 [-0.06, 0.95]	0.24 [-0.25, 0.72]			

Note: * The number of patients with palmoplantar, guttate, inverse, pustular and erythrodermic psoriasis was insufficient to perform the analysis