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PSOdisk is a reliable, intuitive instrument for the evaluation of psychological distress, which strongly correlates with DLQI: a preliminary study

Background: PSOdisk is a 10-item visual instrument, aimed at assessing the burden of disease in patients with psoriasis. *Objectives:* To compare PSOdisk with a scientifically validated questionnaire, the Dermatology Life Quality Index (DLQI), and asses both tools in relation to Psoriasis Severity Index (PASI) and patient acceptance. *Materials & Methods:* Fifty patients with cutaneous psoriasis and/or arthritic psoriasis were recruited. Correlation analysis between PSOdisk and DLQI was performed using Pearson's product-moment correlation coefficient. A multivariate linear regression was carried out to investigate the effect of PASI on PSOdisk and DLQI scores. In addition, we evaluated completion times as well as patient satisfaction for both PSOdisk and DLQI. *Results:* PSOdisk and DLQI mean scores were 22.04 ± 20.56 and 3.35 ± 4.52, respectively. The mean value for PASI was 5.98 ± 5.89 and for age was 55.88 ± 14.09 years. The mean value of Cronbach's coefficient alpha was 0.88 for PSOdisk and 0.90 for DLQI, suggesting good reliability. A significant correlation was found between PSOdisk and PASI, and a statistically significant correlation between DLQI and PASI. Multivariate linear regression analysis demonstrated a statistically significant effect of PASI on both the DLQI score and PSOdisk score. *Conclusions:* PSOdisk demonstrates good correlation with DLQI and PASI, good patient satisfaction, and requires a short completion time.

Key words: daily clinical practice, DLQI, intuitive instrument, PSOdisk, psoriasis, psychological distress

P soriasis is a very common chronic inflammatory disease affecting approximately 2-3% of the world's population [1]. It is characterized by unpredictable periods of spontaneous remission and relapse and often requires long-term treatment [2]. It is frequently characterized by comorbidities such as arthritis, metabolic syndrome, cardiovascular disease, diabetes, stroke, and cancer [2, 3]. Moreover, it puts a significant burden on quality of life by impairing numerous daily occupational and social activities [4, 5]. Therefore, it may be emotionally disabling, paving the way to significant psychosocial disability and distress [6]. Many instruments are available to analyse the impact of psoriasis on quality of life [7]; one of the most frequently used is the Dermatology Life Quality Index (DLQI) [8, 9]. Recently, a new tool has been validated, the PSOdisk [9], a visual, intuitive, Italian, health-related quality of life questionnaire, which was developed to assess the psychosocial burden of psoriasis in patients. The aims of our study were to: (i) compare the PSOdisk, a visual, health-related quality of life instrument, with the more frequently used DLQI; (ii) assess the correlation between disease severity (measured by PASI) and PSOdisk and DLQI scores; and (iii) estimate the average time needed to complete the questionnaires and patient satisfaction for both PSOdisk and DLQI.

Patients and methods

Evaluation of disease severity and health-related quality of life

Between March 2016 and May 2016 at the Dermatology Department of IRCCS A.O.U. San Martino-IST in Genoa, a total of 50 patients were recruited for the study. All patients were affected by psoriasis (PSO) and/or arthritis (PSA) and were taking treatment. Inclusion criteria were: age over 18 years, active disease (independent of disease severity and treatment), ability to complete the questionnaires, and signed informed consent. As the participants were taking treatment, the mean PASI scores were low. All participants were administered the PSOdisk and DLQI questionnaires. DLQI consists of ten items used to assess: severity of symptoms (item 1); disease perception (item 2); impact of disease on daily activities (item 3 and 4), leisure activities (item 5 and 6), work and school activities (item 7), and interpersonal relationships (item 8 and 9); and finally the burden posed by treatment (item 10). The DLQI score is the sum of scores for each question. Tt ranges between a maximum of 30 and a minimum of 0. The PSOdisk consists of 10 questions which are used to assess the general state of

(A)

Skin involvement
10 9 8 7 6 5 4 3 2 1 0

Health
10 9 8 7 6 5 4 3 2 1 0

Shame
10 9 8 7 6 5 4 3 2 1 0

Pain
10 9 8 7 6 5 4 3 2 1 0

Sexual life
10 9 8 7 6 5 4 3 2 1 0

Itch
0 1 2 3 4 5 6 7 8 9 10

Peace of mind
10 9 8 7 6 5 4 3 2 1 0

Sleep
0 1 2 3 4 5 6 7 8 9 10

Work
0 1 2 3 4 5 6 7 8 9 10

Social life
0 1 2 3 4 5 6 7 8 9 10

(B)

Health: Psoriasis has seriously impaired my state of health.
Pain: Psoriasis has caused me a lot of physical pain.
Itch: Psoriasis has led to an unbearable itch.
Sleep: Psoriasis has seriously prevented me from sleeping well.
Social life: Psoriasis has seriously impaired my social life (going out, doing sport, going to the swimming pool, going to the restaurant, seeing friends, etc.)
Work and other daily activities: Psoriasis has caused serious difficulties in my daily activities (at the workplace or at home, studying, enjoying my hobbies, running the household, etc.).
Peace of mind: Psoriasis has seriously impaired my peace of mind.
Sexual life: Psoriasis has made me feel physically unattractive.
Shame: Psoriasis has prevented me from seeing/meeting people the way I would like to (I have felt embarrassed undressing at the swimming pool, doing sport, or at the beach; I have also worn clothes that I would not choose to wear).
Skin involvement: Psoriasis has significantly affected my skin, either due to the extent it has spread or, at least, due to the sensitive areas concerned.
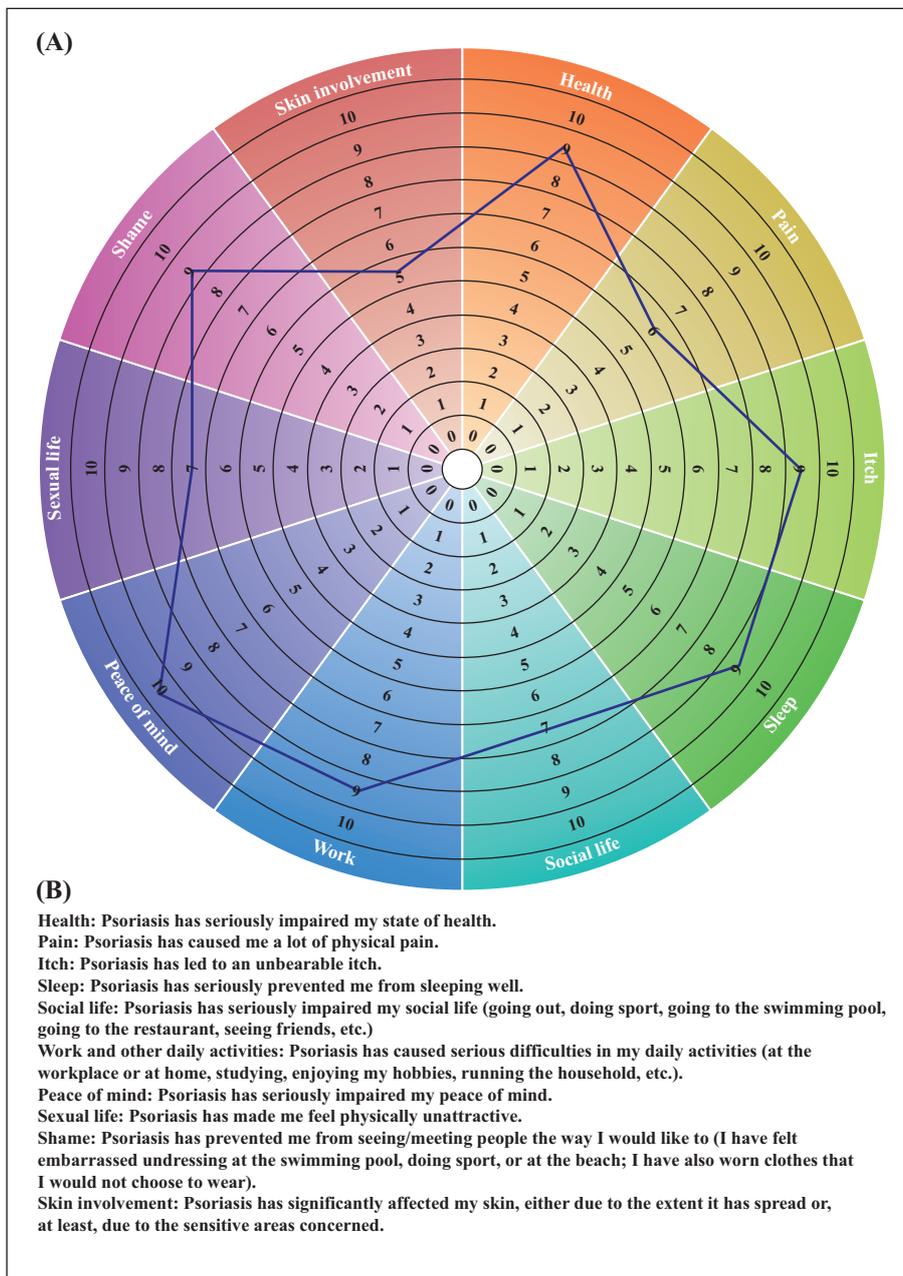
Figure 1. A) Example of a polygon derived from answers to the 10 items. **B)** The ten PSOdisk items: the answers may vary from "absolutely no" to "definitely yes".

health, presence of pain, itchiness, quality of sleep, peace of mind, social life, work satisfaction, sex life, shame, and skin involvement. The answers are given on a 10-point visual analogue scale and then marked on a coloured disk; a polygon is drawn by joining all items. Whenever the burden of the disease decreases (or increases), the area of the polygon shrinks (or grows), thus providing a visual representation of the disease burden. The PSOdisk score is calculated as the sum of the 10 items comprising the PSOdisk questionnaire (*figure 1*). As well as the administration of the DLQI and the PSOdisk, we assessed the severity of disease using the Psoriasis Area Severity Index (PASI). The PASI score is an index used to express the severity of psoriasis; it combines the severity of lesions (erythema, induration, and scaling)

with the percentage of affected area [10]. Both PSOdisk and DLQI questionnaires were handed out to patients who completed them while sitting in the waiting room. Other clinical characteristics, such as age, age at disease onset, and gender, were also collected.

Statistical analysis

Reliability analysis was performed using Item-test and Item-rest correlation, and Cronbach's alpha. All items were associated with Chronbach's alpha coefficients greater than 0.8 and were considered to have a high relevance. During data collection, values far off the mean average were considered as outliers. These values were detected by

Table 1. Descriptive statistics and reliability analysis of PSOdisk and DLQI.

	Descriptive statistics		Reliability analysis		
	Mean (SD)	Range	Item-test correlation	Item-rest correlation	Cronbach's alpha
PSOdisk items					
Health	2.76 (3.11)	0-10	0.85	0.80	0.85
Pain	2.78 (3.20)	0-10	0.67	0.57	0.87
Itching	3.24 (3.68)	0-10	0.77	0.67	0.86
Sleep	2.00 (2.93)	0-10	0.71	0.62	0.86
Sociability	1.28 (2.42)	0-9	0.61	0.52	0.90
Work	1.08 (2.65)	0-10	0.66	0.58	0.86
Serenity	2.48 (2.94)	0-10	0.68	0.59	0.86
Sexuality	0.98 (2.47)	0-10	0.67	0.60	0.86
Shame	1.74 (2.83)	0-10	0.51	0.39	0.88
Skin	3.64 (3.22)	0-10	0.73	0.64	0.86
DLQI items					
Item 1 (symptoms)	1.00 (0.99)	0-4	0.75	0.67	0.89
Item 2 (impressions)	0.38 (0.73)	0-3	0.79	0.74	0.89
Item 3 (daily activities)	0.26 (0.83)	0-5	0.84	0.80	0.89
Item 4 (daily activities)	0.42 (0.73)	0-2	0.60	0.52	0.90
Item 5 (leisure)	0.22 (0.58)	0-3	0.75	0.71	0.89
Item 6 (leisure)	0.24 (0.69)	0-3	0.31	0.21	0.92
Item 7 (work and school)	0.48 (1.11)	0-5	0.83	0.77	0.89
Item 8 (interpersonal relationships)	0.28 (0.67)	0-3	0.66	0.60	0.90
Item 9 (interpersonal relationships)	0.42 (1.18)	0-7	0.89	0.84	0.88
Item 10 (skin treatment)	0.36 (0.98)	0-6	0.86	0.81	0.88

modified Z-scores [11] and values greater than 3.5 were labelled as outliers and not considered for further analysis. Correlation analysis was carried out using the Pearson's product-moment correlation coefficient. Multivariate linear regression was carried out in order to investigate the effect of PASI on PSOdisk and DLQI scores. Potential misleading factors, such as gender and age, were taken into account. In addition, completion times and patient satisfaction were evaluated for PSOdisk and DLQI. Data were acquired and analysed using Stata (Corp. Stata Statistical Software. Release 11.2. Stata Press, College Station (T), USA, 2009). Continuous variables are given as mean ± standard deviation (SD), while categorical variables are given as number of subjects.

Results

Fifty patients (34 men and 16 women) with psoriasis, 28 with only cutaneous lesions, and 22 with additional joint involvement were recruited. The mean age was 56.24 ± 14.18 years (range: 30-82 years). The mean age at disease onset was 36.70 ± 17.86 (range: 8-65 years). The mean duration of disease was 19.54 ± 15.19 years. For PSOdisk, the highest value according to item-test correlation (r = 0.85) was for item 1 (health), while the lowest (r = 0.51) was for item 9 (shame). The item-rest correlation had a similar trend to that of the item-test correlation. In particular, the highest correlation coefficient was identified for health (r = 0.80), while the poorest (r = 0.39) was noted for shame. PSOdisk Cronbach's alpha coefficient mean value
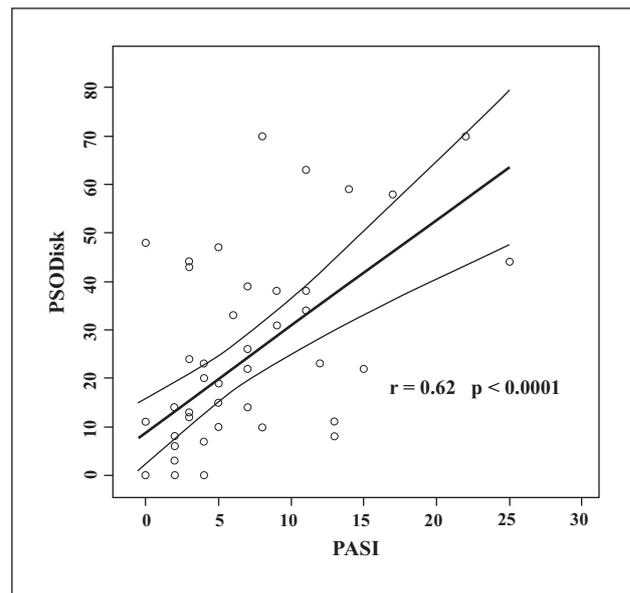

Figure 2. Scatterplot of PSOdisk *versus* PASI. The straight line represents the linear regression of the predicted correlation between PSOdisk and PASI scores.

(internal consistency) was 0.88. Furthermore, excluding each item one by one, Cronbach's alpha increased ($\alpha = 0.90$) only with the deletion of item 5 (sociability). Thus, if we exclude sociability from the PSOdisk, the statistical significance of the correlation between PSOdisk and quality of life score increases. Regarding DLQI, the highest value for

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Table 2. Descriptive statistics and multivariate linear regression of PSOdisk and DLQI scores, corrected by potential confounders, relative to PASI.

| | PSOdisk | | | | | DLQI | | | | |
| | Descriptive statistics | | Linear regression | | | Descriptive statistics | | Linear regression | | |
	n	mean (SD)	β coefficient	Std. error	p value	n	mean (SD)	β coefficient	Std. error	p value
Intercept	-	-	21.24	11.10	0.0621	-	-	4.75	2.09	0.0279
PASI	49	5.98 (5.89)*	2.21	0.40	<0.0001	49	5.98 (5.89)*	0.49	0.09	<0.0001
Gender										
Male	33	18.31 (19.13)**	0	-	-	33	3.58 (4.53)**	0	-	-
Female	16	23.85 (21.27)**	1.00	5.11	0.8464	16	2.88 (4.59)**	0.50	1.10	0.6515
Age (years)	49	55.88 (14.09)*	-0.23	0.17	0.1789	49	55.88 (14.09)*	-0.08	0.04	0.0334

*Mean and standard deviation (SD) of PASI and age, respectively; **mean and SD of PSOdisk and DLQI scores according to gender.*
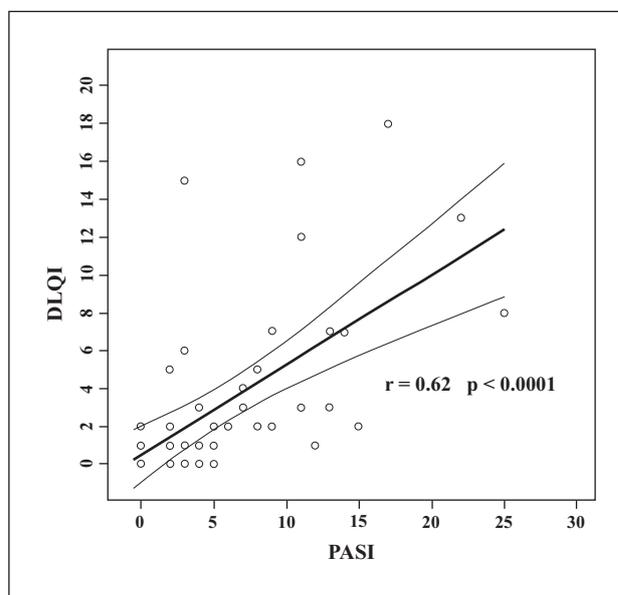

Figure 3. Scatterplot of DLQI *versus* PASI. The straight line represents the linear regression of the predicted correlation between DLQI and PASI scores.

the item-test correlation (r = 0.89) was for item 9 (interpersonal relationships), while the lowest corresponded to item 6 (leisure; r = 0.31). Similar results were found for item-rest correlation. DLQI Cronbach's alpha coefficient mean value was 0.90. Furthermore, excluding each item one by one, Cronbach's alpha improved only by removing item 6 (α = 0.92). The modified Z-score over 3.5 was 4.35 and corresponded to PASI 45. Excluding PASI 45 from our data, the PASI mean value was 5.98 $\pm$ 5.89, ranging from a minimum of 0 (patients in temporary remission) to a maximum of 25 (the most severe case of psoriasis). The mean PSOdisk score was 22.04 $\pm$ 20.56 (range: 0-70). A PSOdisk score equal to or above 8 was shown to have a higher impact on quality of life. The items pain and itching appeared to be those with the heaviest impact. We compared the items of PSOdisk with those of DLQI and found little correlation between the two questionnaires. There was a moderate, statistically significant correlation between PSOdisk and PASI (r = 0.62; *p*<0.0001; *figure 2*). Descriptive statistics and reliability analysis of the PSOdisk and DLQI are presented *table 1*. Multivariate linear regression analysis, corrected for potential confounders such as age and gender (*table 2*), showed a statistically significant effect of PASI on PSOdisk score (β = 2.21; *p*<0.001). In particular, we noted that an increase of one PASI unit was associated with an increase of 2.21 of the PSOdisk score. Concerning the relationship between DLQI and PASI, a significant correlation (r = 0.62; *p*<0.0001) (*figure 3*) was found and the multivariate linear regression analysis (*table 2*) demonstrated a statistically significant effect of PASI on DLQI score (β = 0.49; *p*<0.001). These results showed that by increasing PASI by just one unit, the DLQI score increased by approximately 0.49. The mean completion times were 1 minute and 7 seconds and 1 minute and 33 seconds for PSOdisk and DLQI, respectively. After completing the two instruments, patients were asked which

questionnaire was easier to answer; 20 patients preferred the PSOdisk, 20 patients reported no preference, and the remaining 10 patients considered DLQI preferable.

Discussion

Quality of life is increasingly recognized as an important outcome in dermatology [12]. Many instruments are currently available to assess the severity of psoriasis and/or its impact on patients' quality of life. However, with the exception of studies aimed at testing new drugs, for which the DLQI questionnaire has become standard practice, quality of life assessment instruments are generally not used in daily clinical practice. One may speculate about possible reasons for this: clinicians may overestimate the time required to complete the questionnaires and may not want to introduce them into daily clinical practice; they may be unaware of the possible advantages these instruments can add in terms of adherence and better clinical outcomes; and finally, they may be reluctant, whether consciously or unconsciously, to open Pandora's box regarding psychosocial implications. PSOdisk appears to be an effective device due to its intuitiveness and clear graphic presentation. It does not require any specific training, and was originally designed to be completed by the patient together with the dermatologist in order to support and elicit direct communication between the two. As already mentioned, the polygon area following the completion of the PSOdisk questionnaire is designed to represent the burden of disease during the clinical interview, however, to the best of our knowledge, this has never been studied, which would depend on the sequence of the items, and this may therefore be the subject for further studies.

From our study, itch and pain appear to be strongly correlated with severity of disease. Surprisingly, this correlation is not observed for the items of work and sexuality; one may hypothesize a higher social acceptance of the disease than so far assumed. Our data are similar to those from a previous US survey in which heterosexual women and men, who had psoriasis in areas other than the genitals, were reported to have the same number of sexual partners as those without psoriasis [13, 14]. DLQI structural validity measured using the Cronbach's alpha coefficient was 0.90, similar to that of PSOdisk (0.88). The slight difference between the two tests indicates that the impact of disease on quality of life was accurately evaluated using DLQI as well as PSOdisk. Linear regression analysis demonstrated a relationship between PASI and quality of life. In fact, for an increase of one unit for PASI, the DLQI score increased by 0.49 and the PSOdisk by 2.21. Hence, the impact of psoriasis on quality of life, depending on the severity, was more accurately measured using PSOdisk than DLQI, and these data appear to diverge from previous data [15]. This discrepancy could be explained by a different study methodology and/or by different sample sizes. The mean completion times amounted to 1 minute and 7 seconds and 1 minute and 33 seconds for PSOdisk and DLQI, respectively, thus indicating that the completion of both questionnaires was not perceived by the patients to be a waste of time, even though 60% of them expressed a preference for PSOdisk.

The study has objective limitations: it is based on a limited number of patients (although statistical significance was achieved) as well as a non-homogenous sample; 62% (38/50) of the patients (who were all taking treatment, as previously mentioned) had a PASI lower than 10. However, this second point reflects the normal situation in a psoriasis care unit. Our study suggests a higher "clinical sensitivity" of PSOdisk based on a comparison with the DLQI. The results obtained indicate that the PSOdisk is more reliable, since PASI correlates more clearly with PSOdisk than with DLQI. Our preliminary data also indicate that PSOdisk may be considered as a more versatile instrument which should be further investigated. Future studies should focus on the polygon area rather than the sum of the items, as well as patient and doctor satisfaction, and cross-cultural validation. It is reasonable to assume that the implementation of PSOdisk, an intuitive, easy-to-use instrument in daily clinical practice, might improve doctor/patient communication and increase adherence and facilitate a patient-centred approach, paving the way to better clinical outcomes, and this should therefore be the focus of future studies for this instrument. ∎

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