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INVESTIGATIVE REPORT

Quality of Life Assessment of Patients with Scalp Dermatitis Using the Italian Version of the Scalpdex

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The aim of this study was to assess quality of life in patients with scalp dermatitis using the Italian version of the Scalpdex, and to validate the instrument in Italian. The survey was conducted in outpatients with psoriasis, seborrhoeic dermatitis, alopecia, or follicular lichen. Data were completed on 194 patients, 78% of whom had psoriasis. Scalpdex scores were always higher in women than in men, and in younger people compared to elderly people. The most frequent items were: being ashamed, embarrassed, bleeding scalp, feeling self-conscious, bothered that the condition is incurable, having the choice of colour of clothes affected, having a negative effect on daily life. The Italian Scalpdex showed good internal consistency, test-retest reliability, convergent validity, and responsiveness. In conclusion, the Italian version of the Scalpdex is a useful instrument to measure quality of life in patients with a scalp condition. ***Key words: scalp; quality of life; Scalpdex; validation.***

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Scalp dermatitis is an inflammation of the scalp, which can cause flaky skin, pain, itching, redness, ulceration, and other symptoms. It may thus have a strong impact on quality of life (QoL), both from a psychosocial and symptomatic point of view (1). Scalp dermatitis is mainly due to psoriasis and seborrhoeic dermatitis (SD), 2 conditions whose prevalence is among 1% and 3% of the general population. It has been estimated that scalp involvement is 50–90% in psoriasis, and up to 95% in SD. Thus, scalp dermatitis is a condition involving the QoL of a large number of people. Moreover, management of scalp psoriasis requires long-term strategies, trying to find a balance between the improvement of the condition and the adverse effects associated with the long-term use of treatments (2).

A scalp dermatitis-specific QoL instrument, the Scalpdex (3), has been developed, on the basis of the Skindex (4), an instrument aimed at measuring QoL in patients with dermatological conditions. The authors of the instrument felt that a generic dermatological instrument was not completely suitable to capture the specific impairment due to scalp dermatitis. In fact, they showed that the Scalpdex was more sensitive and more able to detect responsiveness to change in QoL than a generic dermatological questionnaire (3).

The aim of the present study was to translate the Scalpdex into Italian, and to test it for validity, reliability, and responsiveness on a large sample of patients with scalp dermatitis.

MATERIALS AND METHODS

Population

The study population consisted of consecutive patients with a diagnosis of scalp psoriasis, scalp SD, alopecia areata or androgenetica, lichen follicularis, recruited in 4 Italian hospitals: Brescia, Milan, Padua, and Verona. Inclusion criteria were: ≥ 18 years; capability to read and understand Italian; and signed informed consent. Exclusion criteria were: age < 18 years; no comprehension of Italian language; neuroleptic intake; undergoing a systemic therapy for their condition; no compliance. The study was approved by the Ethical Committee of each centre.

Data collection

At baseline, patients who signed the informed consent were asked to complete the following questionnaires: the Scalpdex, the Skindex-29, and the 12-item General Health Questionnaire (GHQ-12). The dermatologists collected socio-demographic and clinical information (e.g., diagnosis, duration), scored the clinical severity using the Physician Global Assessment (PGA), from 0 (very mild) to 4 (very severe), and calculated the Psoriasis Area and Severity Index (PASI) in patients with psoriasis. Information regarding the scalp were abstracted to calculate the "head PASI" (hPASI).

Three to four days after baseline, in order to evaluate the test-retest reliability, the Scalpdex was completed again only by the group of patients with psoriasis. After 6 weeks, the Scalpdex, the Skindex-29, and the GHQ-12 were administered again only to the group of patients with psoriasis. The dermatologist completed again the PASI. The patients evaluated their clinical improvement/worsening on an 8-point scale, from –3 (very much worsened) to +4 (cleared), with 0 meaning no clinical change.

Scalpdex

The Scalpdex is a scalp dermatitis-specific QoL instrument. It has 23 items, with possible answers "never", "rarely", "some-

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times", "often", and "all the time", scored on a scale from 0 to 100 (i.e., 0, 25, 50, 75, and 100). The final scores (symptoms, emotions, and functioning) are calculated by the mean of the item scores pertaining to each scale. Nine items were derived from the Skindex-29 (see below), and 14 from the interview session information.

To obtain a valid Italian version of the Scalpdex, we followed the guidelines for the cross-cultural adaptation of health-related QoL measures (5). The first translation was produced by 2 of us (FS and DL) and revised by another author (DA). A second version was thus created, which was back translated by an English mother tongue literature teacher. The back translation was reviewed by the original Scalpdex authors and a final Italian version was created, also on the basis of the Skindex-29, who had been validated by the same group (6).

Skindex-29

The Skindex-29 (6, 7) is a dermatological QoL instrument which consists of 29 items, with possible answers on a five-point scale, from "never" to "all the time". It is constituted by 3 subscales, measuring symptoms, emotions and functioning.

GHQ-12

The GHQ-12 (8) is a self-administered questionnaire designed to measure psychological distress and to detect current non-psychotic psychiatric disorders, such as anxiety or depression. Answers are given on a 4-point scale and scored as 0-0-1-1. A score of 4 or more indicates the possible presence of anxiety or depression.

Statistical analyses

Descriptive data were reported using percentages and means. Mean values were compared using the *t*-test or ANOVA. The internal consistency of the Scalpdex was assessed by means of Cronbach's α. Construct validity was assessed hypothesising that patients with more severe scalp dermatitis would score higher than patients with a mild disease. The convergent validity was assessed by examining the correlation between Scalpdex scores and comparable scales of the Skindex-29.

The test–retest reliability was measured by the correlation between the scores at baseline and after some days, using the intraclass correlation coefficient. The responsiveness was studied comparing the differences of the Scalpdex score at baseline and after 6 weeks with relation to the clinical change perceived by the patient. Three categories were created: "no or slight improvement", "moderate improvement", and "high improvement or healing". The score variations were evaluated by the Wilcoxon test for dependent data.

All statistical analyses were performed using the statistical package SPSS 13.0.

RESULTS

We obtained complete data on 194 patients: 34 were collected in Brescia, 58 in Milan, 52 in Padua, and 50 in Verona. The study population is described in Table I. The majority of them had a diagnosis of psoriasis (78.4%), and only 5.1% had SD.

In Fig. S1[1] the frequencies of the answers to the 23 items of the Scalpdex are graphically represented. The items to whom the patients answered more frequently "often" or "all the time" were: being ashamed, embarrassed, bleeding scalp, feeling self-conscious, worries that the condition is incurable, having the choice of colour of clothes affected, negative effect on daily life.

Table I. *Description of the study population*

Variables	*n* (%)[a]
Gender, *n* (%)	
Male	106 (54.6)
Female	88 (45.4)
Age, *n* (%)	
<40 years	65 (33.5)
40–59 years	81 (41.8)
≥60 years	46 (23.7)
Education, *n* (%)	
Primary	29 (15.2)
Secondary school	48 (25.3)
High school	80 (42.1)
University	33 (17.4)
Diagnosis, *n* (%)	
Psoriasis	152 (78.4)
Seborrhoeic dermatitis	10 (5.1)
Alopecia areata	5 (2.5)
Alopecia androgenetica	23 (11.9)
Follicular lichen	4 (2.1)
Severity (Physician Global Assessment), *n* (%)	
Very mild	16 (10.3)
Mild	52 (33.3)
Moderate	62 (39.7)
Severe	24 (15.4)
Very severe	2 (1.3)
Duration, *n* (%)	
<10 years	79 (41.4)
10–19 years	50 (26.1)
≥20 years	62 (32.5)
Psoriasis Area and Severity Index, (*n*=152), mean ± SD	7.6 ± 5.9
Head Psoriasis Area and Severity Index, (*n*=152), mean ± SD	1.4 ± 1.0

[a]Totals may vary because of missing figures.

Table II shows the Scalpdex mean scores for the 3 subscales, in different subgroups of different variables. Scores were always higher in women than in men, and in younger people compared to elderly people. Concerning diagnosis, the highest scores were observed in patients with psoriasis. Scalpdex scores were higher in the 10–19 years category of duration compared to shorter and longer duration. In patients with psoriasis, the mean scores of the Scalpdex were higher in patients with higher PASI scores, and the differences were highly significant when considering the hPASI.

The internal consistency of the Scalpdex was very good, with a Cronbach's α of 0.938. The construct validity was verified showing that patients with higher levels of hPASI scored higher than patients with a less clinically severe disease. However, this was not shown for the generic clinical severity PGA score. The test–retest reliability was high: the intraclass correlation coefficient between the 2 measures was 0.868 for symptoms, 0.908 for emotions, and 0.907 for functioning. The convergent validity was measured comparing the Scalpdex scores with the Skindex-29 scores: the correlation was 0.759 for symptoms, 0.778 for emotions, and 0.601 for functioning.

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Table II. *Scalpdex mean scores*

Variable	Symptoms	Emotions	Functioning
Overall	32.5	39.1	34.7
Gender			
Male	29.3	33.8	29.9
Female	36.4*	45.6**	40.5**
Age			
<40 years	37.2	45.9	40.2
40–59 years	32.8	37.5	33.9
≥60 years	24.9*	33.1**	28.5*
Education			
Primary school	23.1	31.9	27.2
Secondary school	35.1	38.3	35.3
High school	35.4	44.9	39.2
University	28.9*	29.9**	27.2*
Diagnosis			
Psoriasis	35.9	40.7	37.6
Seborrhoeic dermatitis	25.0	24.7	19.0
Alopecia areata	16.7	26.7	24.0
Alopecia androgenetica	15.9	37.8	26.6
Follicular lichen	35.4**	37.5	21.2*
Severity (Physician Global Assessment)			
Very mild	29.2	34.4	37.8
Mild	35.3	38.4	35.6
Moderate	36.7	42.9	38.9
Severe/very severe	36.7	41.0	37.9
Duration			
<10 years	31.3	39.9	31.4
10–19 years	37.0	42.1	40.5
≥20 years	29.8	35.1	33.9
PASI (tertiles)			
≤4.24	32.8	36.9	36.7
4.25–7.99	34.6	40.6	36.7
≥ 8.0	38.8	43.0	39.1
Head Psoriasis Area and Severity Index (tertiles)			
≤ 0.74	28.8	32.2	28.4
0.75–1.74	34.7	39.1	35.8
≥1.75	42.8**	49.2**	48.1**

*$p<0.05$, ** $p<0.01$; from *t*-test and ANOVA.

The correlation coefficients between the Scalpdex score and the PASI were very low (0.138, 0.159, and 0.058 for symptoms, emotions, and functioning, respectively). The correlation with the hPASI was a bit higher (0.255, 0.274, and 0.254, respectively).

Concerning responsiveness (Table III), the mean Scalpdex scores were significantly lower in the follow-up compared to baseline in the group "high improvement or healing": from 30.4 to 17.9 for symptoms, from 34.7 to 27.3 for functioning, and from 35.4 to 25.6 for emotions. However, a reduction of the mean scores, even though not so wide, was observed even in the group showing "no or slight improvement", from 40.7 to 36.2 for functioning, and from 44.0 to 39.1 for emotions.

DISCUSSION

In this study, we evaluated the QoL of a large group of patients with scalp dermatitis, using the Italian version of a specific instrument, the Scalpdex. Our population included mainly patients with psoriasis, 12% with alopecia androgenetica, and only 5% with SD.

Given the setting in which the patients were seen, we envisaged that we would have enrolled a limited number of patients with scalp conditions different from psoriasis. However, we collected data on all scalp conditions, to study them and their correlation with other variables at baseline. For the other analyses, we would have had limited study power to study such conditions individually, so we restricted the other procedures to psoriasis.

From this point of view our population was quite different from the original population where the Scalpdex was validated (3), where, out of 52 patients, 25 had psoriasis and 27 had SD. Probably for this reason, the frequencies of the items were not comparable, and items such as "negative effect on daily life" or "it affects the choice of colour of clothes", that had a majority of "no" answers in the original study, were reported, from rarely to all the time, by 91.7% and 87.0% of patients, respectively. This is not surprising, since scalp dermatitis includes several conditions, having different clinical characteristics, and thus a different impact on QoL. For example, desquamation, which is frequent in psoriasis, may affect particular aspects of daily life, such as the choice of the colour of clothes.

Previous studies concerning dermatological conditions with a strong involvement of the scalp (9, 10) generally used generic dermatological QoL instruments to evaluate the impact of the condition on QoL, such as the Dermatology Life Quality Index (11) or the Skindex-29 (7). Those instruments provide important information and allow to compare the disease to all other dermatological conditions. However, the advantage of a specific instrument is that it can describe in detail the specific aspects that are impaired in a given condition.

The Scalpdex was created from the Skindex-29 and it has even some questions in common with it, however detailed questions on the impairment due to the scalp involvement were added, making it an *ad hoc* instrument for scalp conditions.

In this study, the Scalpdex scores were always higher in women than in men, and in younger people compared to elderly people. This is consistent with the results ob-

Table III. *Responsiveness analysis of the Italian version of the Scalpdex: mean values of the Scalpdex subscale scores according to clinical improvement from the patient's point of view*

Patient change	Sc_sym	Sc_sym fu	*p*-value[a]	Sc_emo	Sc_emo fu	*p*-value[a]	Sc_fun	Sc_fun fu	*p*-value[a]
No or slight improvement	41.1	39.0	0.383	44.0	39.1	0.030	40.7	36.2	0.049
Moderate improvement	36.3	28.5	0.041	37.2	33.6	0.007	37.9	30.5	0.012
Large improvement or healed	30.4	17.9	<0.001	35.4	25.6	0.001	34.8	27.3	0.012

[a]Wilcoxon paired test

Sc_sym: Scalpdex symptoms scale; Sc_emo: Scalpdex emotions scale; Sc_fun: Scalpdex functioning scale; fu: follow-up.

tained by Szepietowski et al. (9) in a group of patients with SD, which has a strong involvement of the scalp.

The Italian version of the Scalpdex showed good construct validity, internal consistency, and test–retest reliability. Also the convergent validity with the Skindex-29 was high, however not extremely high, as it has to be, otherwise the instruments would measure the same construct. It is not surprising that the correlation between the Scalpdex and the PASI was low, since it has been demonstrated in psoriasis (12) that clinical severity measures and QoL instruments measure different constructs and are often scarcely correlated.

A discrepancy with the original study on the creation of the Scalpdex concerned the responsiveness. The authors found that the change in the Scalpdex mean scores was not significant when the condition was stable or worse, and it was significant for improvement of condition in functioning and emotions. In our study, the differences were almost always significant, even though they were higher in the "high improvement or healing" group. This probably depended on the short follow-up time in our study, while in the original study the patients were examined again one year later. Also, the 6-week follow-up concerned only patients with psoriasis, while the responsiveness should be tested also in different conditions.

In conclusion, the Scalpdex is a useful instrument to measure QoL in patients with a scalp condition. Specific information can be collected, which is not available in generic instruments. However, the properties of the instrument need to be further studied, in different conditions and at different follow-up time.

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