
Validation of the Dermatology Life Quality Index as an outcome measure for urticaria-related quality of life

Richard D. Lennox, PhD,* and Michael J. Leahy, MBA†

Background: Chronic idiopathic urticaria (CIU) is a debilitating skin disease that affects patients' quality of life (QOL). The Dermatology Life Quality Index (DLQI) assesses QOL parameters across several types of dermatologic conditions. However, an evaluation of the validity of the DLQI for use in CIU patients has not been undertaken, because CIU, unlike other chronic skin conditions, is subject to daily or weekly symptom fluctuations.

Objective: To test the reliability and validity of the DLQI in 2 samples of CIU patients treated with fexofenadine hydrochloride (20, 60, 120, or 240 mg twice daily).

Methods: Data were obtained from 2 similar multicenter, double-blind, randomized, placebo-controlled, parallel-group studies of CIU patients (n = 418 and n = 439). Patients completed the 10-item DLQI during 3 clinic visits (approximately 2 weeks apart). Clinic personnel also recorded patients' symptoms.

Results: The results of the DLQI items were similar to those obtained with other skin disease populations, indicating the presence of relatively symmetrical distributions. Reliability was high, demonstrating the lack of excessive random measurement error (α coefficient = .89 and .87 for samples 1 and 2). Factor analysis resulted in a unidimensional pattern, supporting the use of a total DLQI score. Most DLQI items distinguished patients with varying degrees of QOL impairment, highlighting the sensitivity of this instrument. Construct validity was moderate, providing evidence that the DLQI was responsive to changes in patients' clinical status.

Conclusions: The DLQI is a valid, reliable, and clinically useful outcome measure for assessing QOL in CIU patients.

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INTRODUCTION

It is estimated that 10% to 20% of the US population experiences the dermatologic condition of urticaria at some time in their lives.^{1,2} Urticaria can be characterized by the presence of itchy, erythematous cutaneous swelling; however, several subtypes also exist.³ Approximately 25% of patients with urticaria have wheals of unknown etiology—chronic idiopathic urticaria (CIU).¹ Although their symptoms persist for more than 6 weeks, the severity of the symptoms is subject to daily and weekly fluctuations.

The impact of the clinical symptoms of CIU on patients' quality of life (QOL) is often underestimated. This is echoed in the literature, which contains surprisingly few reports on the impact of CIU on patients' QOL.^{3,4} Of the studies reported, the wheals and pruritus associated with CIU are often so severe and debilitating that they have a profound effect on patients' QOL.⁴

Given the burden of the symptoms of CIU on patients' well-being, effective treatments should improve patients' QOL. Quality of life should be included as an outcome

measure in clinical trials that assess the overall effectiveness of treatment, and several types of questionnaires have been developed to evaluate QOL. One such questionnaire is the Dermatology Life Quality Index (DLQI), which was originally designed in 1994 to evaluate QOL parameters across several types of dermatologic conditions.⁵ The DLQI was designed as a general QOL measure for skin conditions to provide more focused information than that obtained from generic QOL measures, such as the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).

Since the introduction of the DLQI, it has been used in more than 130 studies in patients with different dermatologic conditions and has demonstrated acceptable internal consistency, test-retest reliability, and distributional sensitivity. It has been shown to be more sensitive to clinical changes in individuals with basal cell carcinoma, acne, and atopic dermatitis than the SF-36, the Sickness Impact Profile, the General Health Questionnaire, or the Patient Generated Index.⁶⁻¹⁰ However, it has been hypothesized that in attempting to obtain broad applicability for a range of different dermatologic conditions, the sensitivity to some of the subtypes of urticaria may have been lost.⁵ In particular, it is thought that the daily and weekly symptom fluctuations that are specific to CIU may not be captured by the psychometric assessments used in the DLQI. Therefore, the objective of the present study was to evaluate the validity and reliability of the DLQI in patients with CIU using the results of 2 previously published studies.^{11,12}

* Psychometric Technologies Inc, Hillsborough, North Carolina.

† Health Economics and Outcomes Research Department, Aventis Pharmaceuticals, Bridgewater, New Jersey.

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MATERIALS AND METHODS

DLQI Methodology

The DLQI assesses the impact of a wide range of skin diseases on QOL. In developing this instrument, 120 patients representing more than 32 dermatologic diagnoses were interviewed.⁵ From these interviews, the authors derived a ranked list of 49 aspects of QOL influenced by skin diseases. Based on this list, a 10-item instrument was devised to evaluate DLQI topics that reflect the impact of skin conditions on a person's daily life (Table 1).

Each item is phrased as a question concerning an aspect of QOL. For example, item 6 is addressed through the question, "During the past week, how much has your skin made it difficult for you to do any sport?" The patient responds by checking one of several response options. Responses to items 1 through 6 and 8 through 10 have the options "not at all," "a little," "a lot," and "very much" and are scored as 0, 1, 2, and 3, respectively. Items 3 through 6 and 8 through 10 also have a "not relevant" option that is scored as 0. Item 7 has 2 parts: the first part has the options "yes" and "no," which are scored as 3 and 0, respectively, and the second part has the options "a lot," "a little," and "not at all," which are scored as 2, 1, and 0, respectively. Thus, each of the 10 items can range from 0 to 3. Values in the data sets for missing values or not applicable were recoded as 0.

All items may be summed to form a total score (range, 0–30) indicating the overall degree of QOL, with higher scores indicating greater impairment of QOL. Alternatively, we suggest that items may be aggregated into the following 6 categories: symptoms and feelings (items 1 and 2), daily activities (items 3 and 4), leisure (items 5 and 6), work and school (item 7), personal relationships (items 8 and 9), and treatment (item 10), thus forming 6 separate scores.

Validation

Study Design. Two multicenter, double-blind, randomized, placebo-controlled, parallel-group studies of similar design were conducted to compare the efficacy and safety of fexofenadine in the treatment of CIU. The results of these studies have previously been reported elsewhere.^{11,12}

Both studies were 4 weeks in duration and included patients diagnosed as having CIU who had moderate-to-severe

pruritus. All patients gave written informed consent before study participation. Patients received twice-daily oral doses of placebo or fexofenadine hydrochloride (20, 60, 120, or 240 mg), and they recorded scores for pruritus severity and number of wheals (during the previous 12 hours) in a daily diary. Study participants completed the DLQI during 3 visits to the clinic, which occurred at baseline and approximately every 2 weeks. Efficacy variables included mean daily changes from baseline in pruritus severity, number of wheals, and interference with sleep and daily activities due to urticaria. In addition, clinic personnel and investigators rated patients on the following outcome measures at each visit: intensity of erythema, number of wheals, average diameter of wheals, and extent of skin involved.

In study 1,¹¹ 418 patients from 37 investigative sites were included, whereas study 2¹² included 439 patients from 35 centers. Of the patients who were eligible for inclusion in the studies, 403 in study 1 (sample 1) and 423 in study 2 (sample 2) were included in the final QOL intent-to-treat populations and, therefore, in the present analysis.

Statistical Analysis. The primary objective was to show that the DLQI is capable of measuring the QOL dimensions associated with CIU through the scoring algorithm originally designed by the authors of the scale. A set of traditional psychometric analyses were performed to test the reliability, validity, and factor structure of the DLQI and its correlations with clinical criteria in samples of urticaria patients.^{11,12} The analysis followed a progressive strategy that began with a simple analysis of the distributions and continued with additional consideration of other, more refined, item and scale characteristics.

To investigate item distributions across the DLQI scale, the mean and SD for each item were determined to establish the level of data skewness. The internal consistency of the 10-item set was evaluated using the α coefficient, which gauges the amount of intercorrelation that exists among the 10 items of the DLQI. Principal components analysis of the 10 DLQI items was performed to explore the structure of the correlations matrix without being required to specify a priori the number of factors present. A confirmatory factor analysis tested the unidimensionality of the scale. A graded item response model determined how each item performed in terms of its ability to discriminate across levels of QOL and the locations on the dimension at which each item best discriminates. Sensitivity to clinical change was evaluated by correlating the DLQI difference score with difference scores from each of the patient- and investigator-based outcomes.

RESULTS

Clinical Findings

In both samples of patients, baseline characteristics and symptom assessments were similar, as previously reported.^{11,12} In study 1, all 4 fexofenadine doses were statistically superior to placebo in reducing the pruritus score and the number of wheals during the 4-week treatment period

Table 1. Details of the 10-Item List Included in the Dermatology Life Quality Index

Item No.	Description
1	Felt itchy, sore, painful
2	Felt embarrassed
3	Interfered with shopping
4	Influenced clothes
5	Affected social leisure
6	Skin difficulty with sports
7	Created difficulty with work or study
8	Produced problems with partner
9	Created sexual difficulties
10	Treatment caused problems at home

($P \leq .01$).¹¹ Similarly, in study 2, all 4 doses of fexofenadine were statistically superior to placebo for mean pruritus score, mean number of wheals, and mean total symptom score ($P \leq .02$).¹²

In both studies, patients receiving fexofenadine experienced significantly less interference with sleep and daily activities than patients receiving placebo ($P \leq .02$). Adverse events occurred with similar incidence in all treatment groups, with no dose-related increases in any events.^{11,12}

Item Distribution Analysis

The frequency distributions (mean and SD) for each of the 10 items of the DLQI were free of floor and ceiling effects (Table 2).

Internal Consistency Tests

Analysis of the α coefficients, as a means of determining internal consistency, showed that the 10 items of the DLQI were also reliable across both studies of CIU patients (study 1: $\alpha = .89$; study 2: $\alpha = .87$). Further analysis revealed that the internal consistency could not be improved by removing any single item of the DLQI. This pattern was consistent across the 2 CIU populations, highlighting that the DLQI was reliable in 2 independent groups of CIU patients.

Exploratory Factor Analysis

The results of the exploratory factor analysis are given in Table 3. The α coefficients were greater than .60 in both samples except for those for item 1. However, the α coefficient of .37 in sample 2 exceeds the traditional salience criterion of .30, and, therefore, the item does not compromise the reliability of the scale in either sample. This pattern shows a strong level of intercorrelations among the items and sug-

Table 3. Factor Loadings of a Single Principal Factor of the Dermatology Life Quality Index Items

Item No.	Abbreviated item	α coefficient	
		Sample 1	Sample 2
1	Itchy, sore, painful	.50	.37
2	Embarrassed	.64	.56
3	Interfered with shopping	.78	.78
4	Skin influenced clothes	.65	.64
5	Affected social leisure	.78	.80
6	Skin difficulty with sports	.67	.71
7	Problems with work or study	.64	.57
8	Problems with partner	.71	.65
9	Sexual difficulties	.67	.65
10	Problems at home	.60	.69

gests that the DLQI is unidimensional and consistent with the single-score algorithm approach to rating the scale.

Confirmatory Factor Analysis

To test the unidimensionality of the 10-item scale, a confirmatory factor analysis was performed. The root-mean-square error of approximation estimate was 0.12, the goodness-of-fit index was 0.89, and the Benter-Bonett index was 0.88. This analysis supports either a 1- or 2-factor model, with the correlations from the 2-factor model indicating that the total score of all 10 items is interpretable as a global score. Table 4 presents the standardized loadings of the items in both samples. The results closely resemble the principal components analysis, but, as expected, they are not identical. All standardized loadings are significantly different from zero and exceed the traditional .30 saliency criterion used in exploratory factor analysis

Table 2. Dermatology Life Quality Index Scores in Chronic Idiopathic Urticaria Patient Populations

Item No.	Item	Score, mean (SD)	
		Sample 1	Sample 2
1	During the past week, how itchy, sore, painful, or stinging has your skin been?	2.17 (0.73)	2.13 (0.76)
2	During the past week, how embarrassed or self-conscious have you been because of your skin?	1.29 (1.03)	1.32 (0.95)
3	During the past week, how much has your skin interfered with you going shopping or looking after your home or garden?	0.64 (0.88)	0.71 (0.85)
4	During the past week, how much has your skin influenced the clothes you wear?	1.26 (1.06)	1.22 (1.03)
5	During the past week, how much has your skin affected any social or leisure activities?	0.86 (0.93)	0.83 (0.87)
6	During the past week, how much has your skin made it difficult for you to do any sport?	0.64 (0.93)	0.62 (0.93)
7	During the past week, has your skin prevented you from working or studying? If no, over the last week, how much has your skin been a problem at work or study?	0.64 (0.93)	1.23 (1.03)
8	During the past week, how much has your skin created problems with your partner or any of your close friends or relatives?	1.3 (0.99)	0.65 (0.86)
9	During the past week, how much has your skin caused any sexual difficulties?	0.60 (0.85)	0.4 (0.78)
10	During the past week, how much of a problem has the treatment for your skin been, eg, by making your home messy or by taking up time?	0.43 (0.81)	0.55 (0.79)

Table 4. Standardized Coefficients for a 1-Factor Confirmatory Factor Analysis of the Dermatology Life Quality Index Items

Item No.	Abbreviated item	α coefficient	
		Sample 1	Sample 2
1	Itchy, sore, painful	.50	.34
2	Embarrassed	.65	.55
3	Interfered with shopping	.78	.80
4	Skin influenced clothes	.65	.63
5	Affected social leisure	.79	.83
6	Skin difficulty with sports	.68	.72
7	Problems with work or study	.64	.56
8	Problems with partner	.69	.65
9	Sexual difficulties	.66	.65
10	Problems at home	.60	.67

($P < .001$). The fact that almost all α coefficients are greater than .50 suggests that the items can be considered good indicators of the underlying construct.

Item Response Analysis

Item response theory analysis, using Samejima's Graded Model, showed that most items (except for item 1) had moderate discriminating power and could differentiate people with high vs low levels of QOL, thus demonstrating the content validity and sensitivity across the entire range of variables (Table 5).

The "b" parameters indicate that most of the items were sensitive to the entire range of the construct. For items 1 through 5 and 7, the lowest response option (1 = a little) was largely associated with negative values below the mean, and the highest response option (3 = very much) was associated with positive values above the mean. Items 6 and 8 through 10 were strongest at the upper range of the construct, suggesting that they are best suited for people with greater impairment of QOL. Taken together, these results suggest that the DLQI can distinguish people with varying degrees of impairment of QOL.

Table 6. Correlations between Changes in Dermatology Life Quality Index (DLQI) Scores and Clinical Outcomes*

Outcome	Correlation coefficient (r)	
	Sample 1	Sample 2
Number of wheals	0.38	0.34
Itching	0.45	0.40
Intensity of erythema	0.37	0.33
Diameter of wheals	0.39	0.35
Extent of skin involved	0.26	0.25
Interference with daily activities	0.30	0.21
Interference with sleep	0.29	0.29

* $P < .001$ for all (changes in the total DLQI scores and clinical outcome variables).

Predicting Clinical Change (Tests of Construct Validity)

All correlations in the construct validity assessments were significantly different ($P < .001$) and were generally of medium magnitude ($r = 0.21$ – 0.45) (Table 6). This level of correlation is consistent with the theoretical distinctiveness of QOL and clinical status and, at the same time, the assumption that QOL is primarily driven by clinical status.

The relationship between the DLQI and patient-based outcomes (ie, interference with sleep and interference with daily activities) was examined to determine whether the DLQI possesses discriminant validity (ie, the extent to which different methods are used to measure different constructs). The correlations ranged from 0.21 to 0.37, which suggests that the DLQI measures a distinct construct.

DISCUSSION

Chronic idiopathic urticaria is a chronic and often debilitating skin disease that can have a profound effect on patients' QOL and ability to perform usual daily activities.⁴ However, until recently, little research had been undertaken on the impact of CIU on QOL parameters or to validate the evaluation tools available.

Table 5. Item Response Parameters for the Dermatology Life Quality Index (DLQI) Items

Item No.	Abbreviated item	Sample 1				Sample 2			
		<i>a</i>		<i>b</i>		<i>a</i>		<i>b</i>	
		<i>a</i>	<i>b1</i>	<i>b2</i>	<i>b3</i>	<i>a</i>	<i>b1</i>	<i>b2</i>	<i>b3</i>
1	Itchy, sore, painful	1.24	−5.68	−1.51	0.56	0.70	−7.01	−2.05	1.00
2	Embarrassed	1.63	−1.06	0.43	1.28	1.34	−1.32	0.50	1.80
3	Interfered with shopping	2.67	0.16	1.11	1.87	2.63	0.02	1.21	2.10
4	Skin influenced clothes	1.67	−0.82	0.34	1.32	1.58	−0.76	0.43	1.62
5	Affected social leisure	2.66	−0.25	0.81	1.72	2.69	−0.24	1.08	1.89
6	Skin difficulty with sports	1.93	0.18	1.18	1.79	1.98	0.31	1.27	1.89
7	Problems with work or study	1.68	−1.14	0.49	1.38	1.33	−1.00	0.74	1.54
8	Problems with partner	2.14	0.21	1.22	2.17	1.63	0.18	1.49	2.45
9	Sexual difficulties	2.57	0.65	1.26	2.04	2.00	0.78	1.79	2.25
10	Problems at home	1.65	0.37	1.57	2.54	1.90	0.35	1.60	2.55

Abbreviations: *a*, the discrimination parameter; *b*, the threshold parameter; *b1*, *b2*, *b3*, different response options on the DLQI.

In addition to generic QOL tools such as the SF-36, disease-specific QOL assessments, such as the DLQI, have been developed. However, although more focused than generic QOL tools, the DLQI was designed to evaluate QOL parameters across several types of dermatologic conditions, such as psoriasis, acne, and urticaria. Consequently, it has been postulated that this questionnaire may not be sensitive enough to detect the impact of the daily and weekly fluctuations associated with the symptoms of CIU on QOL. This is the first study to validate the use of the DLQI as an outcome measure for assessing QOL in a large sample of CIU patients.

The results of this validation study provide convincing evidence that the DLQI is an appropriate outcome measure for use in patient populations with CIU. The findings presented herein are consistent with psychometric evidence for the DLQI reported in other disease populations, indicating the presence of relatively symmetrical distributions.⁶ In addition, the distributions seem to be unaffected by excessive ceiling or floor effects that would render the scale insensitive to patients who are outliers in the population.

The 10 items of the DLQI scale were found to be internally consistent, and it was evident that no single item unduly influenced the α coefficient. Viewed from the classic psychometric model, the internal consistency shows that the item set seems to be free of excessive random measurement error of the type that would decrease the reproducibility of this tool. From these results, we can conclude that the DLQI is a relatively sensitive test of QOL in patients with CIU.

It was previously suggested herein that the 10 items of the DLQI could be aggregated into 6 categories—symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment—to generate 6 separate scores. However, the apparent unidimensionality of the 10 items of the DLQI reported herein supports the use of a total item score. The high intercorrelation among the variables suggests that the 6 categories are likely to have little effect in predicting clinical outcomes. Therefore, physicians should be wary of interpreting the clinical value of the DLQI based on 6 separate scores. It seems that the results based on the 6 scores may lack discriminant validity and may, therefore, not accurately represent the overall improvements in clinical outcomes.

In this study, the item response modeling analyses revealed that the DLQI could distinguish patients with varying degrees of impairment of QOL. The DLQI was also sensitive to changes in clinical status as evaluated by patient- and investigator-based outcomes. Therefore, the DLQI should be considered a valuable tool for assessing treatment-related outcomes in patients with CIU in clinical practice.

In summary, the symptoms of CIU clearly have a significant impact on patients' activities of daily living. Measurement of QOL is becoming increasingly important to evaluate the overall effectiveness of therapy and the impact of the symptoms of CIU on individuals. Our findings demonstrate that the 10-item DLQI is a valid, reliable, and clinically useful outcome measure for assessing QOL in patients with CIU.

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Requests for reprints should be addressed to:

Richard D. Lennox, PhD

Psychometric Technologies Inc

402 Millstone Dr

Suite A

Hillsborough, NC 27278

E-mail: rlennox@mindspring.com