

Baseline Quality of Life As Measured by Skindex-16+5 in Patients Presenting to a Referral Center for Patch Testing

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Background: The impact of skin disease on health-related quality of life (QoL) is often underrecognized, and there is little research about health-related QoL in patch-tested populations.

Objective: A pilot study to assess baseline QoL in dermatitis patients referred to a specialized center for patch testing.

Methods: A convenience sample of patients presenting for patch testing ($n = 107$) completed a survey, Skindex-16+5, which measures QoL in four domains: symptoms, emotions, functioning, and occupational.

Results: Responses were indexed from 0 (never bothered) to 100 (always bothered). Emotions (mean, 67; SD $\pm$ 27) and symptoms (mean, 60; SD $\pm$ 27) demonstrated the lowest QoL. Patients with hand involvement had a worse QoL in all areas, including the occupational domain, compared to patients without hand involvement. Limitations of the study included the referral clinic population and convenience sample. Survey questions added to Skindex-16 regarding the occupational domain have not been validated.

Conclusions: Patients referred for patch testing endorse a highly negative impact of the disease on their emotional QoL and are also greatly bothered by symptoms. Patch-tested patients with hand dermatitis had a significantly lower QoL across all areas as compared to tested patients without hand involvement. Facial involvement, duration of skin problem, atopic history, occupation relationship, or positive patch-test results were not correlated with QoL.

SKIN DISEASES, like other diseases, may have a functional impact but are notably different from other diseases in that they affect appearance and are outwardly visible. Itching can also be a vexing, tiresome, and difficult-to-control problem. The effect of chronic dermatitis on social and emotional functioning is often very significant yet is often underrecognized and little reported.

The impact of disease on the patient's quality of life has gained increased attention as an important outcome measure, particularly as it relates to resource allocation, treatment, or other interventions. The physician's clinical judgment of disease impact does not necessarily correlate with the patient's assessment. Additionally, the clinical

severity of a skin disease does not necessarily correlate with the effect that the condition has on various aspects of a patient's life. Recent study designs have aimed to capture this increasingly important outcome measure of health-related quality of life.¹ The ability to return to work, disruption of work, improvement of dermatitis with time, and quality of life (QoL) are among outcome measures that have been studied in patients with allergic and irritant contact dermatitis. Some disease-specific QoL tools have been published, including one for psoriasis² and one for atopic dermatitis.³ The QoL assessment tools that have been most commonly applied to studying contact dermatitis patient populations include (1) the Dermatology-Specific Quality of Life (DSQL) questionnaire,^{4,5} (2) the Dermatology Life Quality Index questionnaire (DLQI),⁶⁻⁸ and (3) a modified version of Skindex-16⁹ (with questions pertaining to the occupational domain) known as Skindex-16+5. Developed by Chren, Skindex was refined over time to the present Skindex-16, a validated and comprehensive general dermatology-related QoL questionnaire.¹⁰ Skindex-16 can be quickly used in a clinic setting and is an internally consistent, reliable, and responsive instrument. Skindex-16 can be used for discriminative purposes, that is, to compare QoL among patients with different skin dis-

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eases.¹⁰ It can also be used for evaluative purposes, that is, to measure QoL differences longitudinally over time. The same five questions pertaining to occupational impact that were used by Kadyk and colleagues in their study of QoL after patch testing were added to Skindex-16 by this author (K.A.Z.) to yield the questionnaire tool (Skindex-16 +5) used in this study.⁹

The objective of this pilot study was to measure baseline QoL indexes by Skindex-16+5 in our population of patients referred for patch testing. (Skindex-16 and Skindex-16+5 had not been used previously to measure baseline QoL in a patch-tested population.) A secondary objective was to identify demographic or clinical data that correlated with QoL. We hypothesized that hand dermatitis and generalized dermatitis would be variables associated with a poorer QoL score. We also expected a greater impact (i.e., a worse QoL score) on patients with a longer duration of disease. We compared our results with those obtained in other studies that used Skindex-16 and Skindex-16+5.

Methods

Approval was obtained from our institutional review board Committee for the Protection of Human Subjects (CPHS #16844). The Dartmouth-Hitchcock Medical Center patch-test clinic is a regional referral center and one of 13 participants in the North American Contact Dermatitis Group (NACDG). A convenience sample of patients presenting to the patch-test clinic between October 2002 and June 2004 were asked to fill out the Skindex-16+5 QoL survey. This survey was voluntary and was administered on the first day of patch testing, prior to any patch application. Because of occasional busy clinical circumstances or staffing changes, most but not all of the patch-tested patients were asked to complete the survey. Very few patients who were asked to complete the survey declined. Survey information was anonymous but was linked by identification number to individual demographic, disease-related, and diagnostic information.

Demographic and limited prepatch-test clinical data were collected from a standardized data collection sheet, which allowed three possible sites of dermatitis to be listed. Involvement of a particular site was determined as “yes” if it was listed as any one of the three sites. Also recorded were the duration of the skin problem that led to patch testing; the patient’s reported history of hay fever, childhood atopic eczema, or asthma; and whether the problem was related to the patient’s occupation (yes or

no). Patients were patch-tested with the NACDG standard screening tray and with selected supplemental allergens or allergen trays if deemed appropriate. Allergens were removed in 48 hours, and readings were taken at 48 and 96 hours. Postpatch-test information that was collected included final diagnoses, occupational association, and the number of relevant positive patch-test reactions.

Skindex-16+5 assesses the bother of skin disease in four domains: symptoms, emotions, functioning, and occupational impact. Survey responses are given as a Likert scale from 0 (never bothered) to 6 (always bothered). This scale was then translated into an index from 0 (never bothered) to 100 (always bothered).¹¹ A higher QoL score indicates a greater QoL impairment because it reflects answers more weighted toward the “always bothered” anchor of the scale.

Skindex-16+5 was modified by asking the patient to consider the bother of their skin condition over the previous month. Five occupational questions were added by this author (K.A.Z.), based on clinical experience of complaints of patients with work-related problems. This modified Skindex-16+5 questionnaire is shown in Table 1.

Data were entered into a *Microsoft Excel 2003* (Microsoft Corporation, Redmond, WA) spreadsheet and analyzed with *R: A language and environment for statistical computing* statistical software (R Development Core Team, Vienna, Austria).

Descriptive statistics were used to describe the demographic and clinical features of this patient population. To compare the characteristics of those who completed the survey and those who did not during this time period, *t*-tests and Wilcoxon rank sum tests were used. The mean global QoL was calculated by omitting the results of the occupation questions and weighting the results of each question equally for the 16-question Skindex-16; the mean global QoL of Skindex-16+5 was calculated with the equal weighting of each of the 21 questions. Linear regression, univariate and adjusted, was used to assess the association of QoL with the following variables: age; gender; duration of rash prior to patch testing; distribution of rash (hand, face, scattered or generalized); history of hay fever, asthma, or eczema or any one of those three (atopic history); number of relevant positive patch-test reactions; and relationship of the condition to an occupation. Adjusted results were not reported owing to their similarity to the univariate results. *p* Values were reported without adjustment (eg, Bonferroni) to account for inflation of the overall type I error rate due to multiple testing (eg, overall QoL and the four subscales). Because this was an exploratory analysis, adjustments for multiple comparisons were not made.

Table 1. Skindex-16+5 Questionnaire*

Symptoms	(1) Your skin itching (2) Your skin condition burning or stinging (3) Your skin condition hurting (4) Your skin condition being irritated
Emotions	(5) The persistence/reoccurrence of your skin condition (6) Worry about your skin condition (7) The appearance of your skin condition (8) Frustration about your skin condition (9) Embarrassment about your skin condition (10) Being annoyed about your skin condition (11) Feeling depressed about your skin condition
Functioning	(12) The effects of your skin condition on interactions with others (13) The effects of your skin condition on desire to be with people (14) Your skin condition making it hard to show affection (15) The effect of your skin condition on your daily activities (16) Your skin condition making it hard to work or do what you enjoy
Occupational Impact	(17) Concerns that you may need to leave your job due to your skin condition (18) Fear for your financial future because of your skin condition (19) Concerns that your interactions with co-workers will be difficult because of your skin condition (20) Difficulty using your hands at work because of your skin condition (21) Fear of being fired from your job because of you skin condition

*Patients are asked, "During the past month, how much have you been bothered by..."

Results

Demographics and Clinical Features

Demographics and clinical features were similar among patients who completed the survey ($n = 107$) as opposed to those who did not ($n = 58$) (Table 2). Only patients with facial dermatitis were less likely to complete the survey. Clinical and demographic variables and their association with QoL are reported in Table 3. Hand involvement and age were the only variables correlated with QoL. Duration of rash, facial involvement, scattered or generalized involvement, atopy, gender, positive patch-test results, or relationship of condition to occupation were not correlated with baseline QoL.

Hand Involvement

As hypothesized, hand involvement was predictive of a significant effect on QoL in comparison to no hand involvement in all areas evaluated (symptoms, emotions, functioning, and relationship to occupation) (Table 4).

The association of hand involvement with QoL was significant ($p < .001$) when adjusted for age (the only other variable associated with QoL), as were the subscores of symptoms ($p = .0001$), emotion ($p = .005$), functioning ($p = .0008$), and relationship to occupation ($p < .0001$). For patients with hand involvement, emotion scores for frustration, annoyance, persistence, embarrassment, and appearance were significantly worse than those for patients who had no hand involvement. Symptom QoL scores of patients with hand involvement showed the second greatest negative impact; irritation and hurting scores were significantly higher for those with hand involvement than for those with no hand involvement. Itching and burning scores for those with and those without hand involvement were not significantly different although burning had the lowest overall symptom score. This is not surprising in patients suspected of having allergic contact dermatitis because burning is generally associated with irritation rather than allergy. Functioning scores regarding the effect of the skin condition on interaction with others, desire to be with people, ability to show affection, daily activities, and ability to work or do what

Table 2. Comparison of Patients Who Completed Skindex-16+5 with Those Who Did Not

	Completed Skindex 16+5	Did Not Complete Skindex-16+5
<i>n</i>	107	58
Average age (yr)	50	47
Male gender	38 (36%)	23 (40%)
Hay fever history	34 (32%)	16 (28%)
Asthma history	24 (22%)	11 (19%)
Eczema history	24 (22%)	11 (19%)
Hands affected*	37 (35%)	19 (34%)
Face affected†	17 (16%)	16 (29%)
Average duration of rash (mo)	18	12

*Includes distribution in any of the three sites of involvement that could be recorded.

†Patients with facial involvement were less likely to complete the survey ($p = .04$).

one enjoys were significantly worse for patients with hand involvement than those for patients without hand involvement.

Occupational QoL

Sixteen percent of patients ($n = 17$) had an occupation-related condition. The hands were involved in 71% ($n = 12$) of occupational cases. Hand involvement was significantly associated with higher occupational QoL scores than those of patients without hand involvement (see Table 4).

Global QoL

Mean global QoL scores and individual question and domain mean subscores (emotions, symptoms, function-

ing, and occupational) are presented in Table 4. Emotional QoL had the worst QoL subscores; patients were bothered by frustration, annoyance, persistence, worry, appearance, embarrassment, and depression. Symptoms had the second greatest impact; patients reported a high degree of bother by itching and irritation, but burning and hurting symptoms had less impact.

Discussion

QoL was significantly negatively affected for a heterogeneous group of patients who were referred to a tertiary referral center for patch testing, most notably for patients with hand dermatitis and in the domains of emotions and symptoms. Our patients had a median skin disease

Table 3. Descriptive Statistics of the Patient Population and Univariate Associations with Quality of Life*

	Median (Range or %)	QoL Coefficient	95% CI	p Value
Age (yr)	50 (17–83)	−0.4	−0.7–0.0	.03
Duration of problem (yr)	3.4 (0.1–40.0)	0.4	−0.4–1.2	.35
Male sex	38 (36%)	2.0	−8.7–12.7	.72
Hand involvement (yes)	37 (35%)	23.2	13.9–32.5	< .0001
Face involvement (yes)	17 (16%)	−4.6	−17.7–8.5	.49
Scattered, generalized involvement (yes)	32 (30%)	−2.7	−14.2–8.8	.64
Some positive patch-test reactions	74 (69%)	−0.6	−11.5–10.3	.91
History of eczema	24 (22%)	8.5	−3.3–20.2	.15
History of asthma	24 (22%)	1.8	−10.1–13.7	.76
History of hay fever	34 (32%)	−1.2	−12.0–9.6	.83
Any atopic marker	54 (51%)	−2.4	−12.5–7.7	.64
Occupational relationship (yes)	17 (16%)	8.9	−3.7–21.5	.16

QoL = quality of life.

*Unadjusted associations using linear regression analysis.

Table 4. Quality of Life Subscores for Patients with and without Hand Involvement and for All Patients[†]

	Hand Involvement, n = 37 [‡] (mean ± SD)	No Hand Involvement, n = 70 (mean ± SD)	p Value [§]	Mean QoL Subscore, N = 107 (mean ± SD)
Global QoL Skindex-16+5	65 ± 18	42 ± 23	****	49 ± 24
Global QoL for Skindex-16 (omitting occupational questions)	72 ± 16	51 ± 25	****	59 ± 25
Domain: Symptoms	74 ± 15	53 ± 27	****	60 ± 27
Itching	80 ± 20	70 ± 28	*	73 ± 26
Irritation	82* ± 18	63 ± 29	****	70 ± 27
Burning	58 ± 32	45 ± 36	**	50 ± 35
Hurting	65* ± 26	33 ± 34	****	43 ± 35
Domain: Emotions	78 ± 19	60 ± 29	****	67 ± 27
Frustration	87* ± 21	72 ± 32	****	77 ± 30
Annoyance	76* ± 21	70 ± 32	*	75 ± 30
Persistence	83* ± 23	70 ± 33	**	75 ± 31
Embarrassment	70* ± 32	43 ± 38	****	53 ± 39
Appearance	73* ± 30	56 ± 34	***	62 ± 34
Worry	77 ± 29	67 ± 34	*	70 ± 33
Depression	58 ± 34	47 ± 37	*	50 ± 36
Domain: Functioning	58 ± 27	34 ± 30	****	43 ± 31
Interactions	57* ± 34	38 ± 35	**	45 ± 36
Desire to be with people	52* ± 33	32 ± 36	***	38 ± 45
Show affection	48* ± 35	28 ± 36	***	35 ± 37
Daily activities	63* ± 30	37 ± 34	****	48 ± 35
Work	70* ± 30	37 ± 36	****	48 ± 37
Domain: Occupational	40 ± 33	12 ± 19	****	22 ± 27
Concerned may need to leave job owing to skin condition	43* ± 41	18 ± 31	***	27 ± 37
Fear of financial future because of skin condition	47* ± 43	17 ± 31	****	27 ± 38
Concerned that interactions with co-workers will be difficult	37* ± 37	10 ± 21	****	20 ± 31
Difficulty using hands at work	52* ± 39	8 ± 21	****	23 ± 35
Fear of being fired because of skin condition	23* ± 37	5 ± 19	**	12 ± 28

QoL = quality of life.

[†]Higher scores indicate worse QoL.[‡]Includes patients with hand involvement in any of the 3 sites recorded.[§]p Values are not corrected for multiple comparisons.^{||}Mean domain QoL score. All participants, working or not, completed the occupational questions.

*.01 < p ≤ .05; **.001 < p ≤ .01; ***.0001 < p ≤ .001; ****p ≤ .0001.

duration of 18 months (mean, 3.5 years); contrary to our suspicion, duration of disease, and generalized dermatitis were not associated with a poorer QoL score.

Comparison with Other Studies

Kadyk and colleagues used Skindex-16+5 to assess QoL in a patch-tested population based at a referral center.⁹ However, their study assessed QoL after patch testing.

Also, their population differed by including only patients diagnosed with allergic contact dermatitis and having relevant positive patch-test results. Skindex-16+5 (by mail) was completed at some point (< 6 months to > 36 months) after testing. Their findings and ours are compared at the bottom of Table 5. They reported that patients who filled out the questionnaire less than 6 months after patch testing had the worst QoL scores; those patients who had been assessed and tested 6 to 12 months

Table 5. Comparison of Skindex-16 Scores (mean $\pm$ SD) from Published Studies

Lead Author (Year)	Reference	Diagnosis (n)	Global QoL (mean $\pm$ SD)	Symptoms (mean $\pm$ SD)	Emotions (mean $\pm$ SD)	Functioning (mean $\pm$ SD)	Comments
Chren (2001)	10	Eczematous dermatitis, including seborrheic dermatitis (84)	NR	42 $\pm$ 31	52 $\pm$ 30	24 $\pm$ 29	—
		Psoriasis (27)	NR	49 $\pm$ 29	68 $\pm$ 25	39 $\pm$ 17	—
		Acne vulgaris (38)	NR	31 $\pm$ 24	75 $\pm$ 23	38 $\pm$ 30	—
		Warts (33)	NR	23 $\pm$ 23	48 $\pm$ 31	24 $\pm$ 31	—
		Actinic keratosis (64)	NR	24 $\pm$ 23	35 $\pm$ 29	14 $\pm$ 23	—
		Basal cell carcinoma (74)	NR	21 $\pm$ 24	33 $\pm$ 26	12 $\pm$ 22	—
		Benign growths (54)	NR	15 $\pm$ 20	34 $\pm$ 29	12 $\pm$ 21	—
		Squamous cell carcinoma including in situ lesions (10)	NR	15 $\pm$ 15	26 $\pm$ 22	20 $\pm$ 17	—
Hundley (2006)	15	Dermatomyositis (71)	51 $\pm$ 22	17 $\pm$ 8	33 $\pm$ 13	18 $\pm$ 10	Females had worse QoL, higher with disability. Skindex-16 and DLQI used to measure QoL.
O'Reilly (2006)	16	Solid-organ transplant recipients (33)	26 $\pm$ 22	18 $\pm$ 21	37 $\pm$ 30	18 $\pm$ 22	Kidney and liver transplantation patients. Overall QoL influenced by time after transplantation, primarily affecting emotions scale. Females had worse overall QoL.
Kawashima (2007)	17	Atopic dermatitis: baseline (415)	52 $\pm$ 21	49 $\pm$ 26	68 $\pm$ 26	52 $\pm$ 21	Investigation of standard therapy impact on QoL at 4 and 12 weeks.
		Follow-up, 12 weeks	36 $\pm$ 23	36 $\pm$ 25	46 $\pm$ 28	23 $\pm$ 24	Patients in moderate and severe disease groups had significant improvement in all three subscores.

Table 5. Continued

Lead Author (Year)	Reference	Diagnosis (n)	Global QoL (mean $\pm$ SD)	Symptoms (mean $\pm$ SD)	Emotions (mean $\pm$ SD)	Functioning (mean $\pm$ SD)	Comments
Kadyk (2003)	9	Follow-up study of patients with positive patch-test results (149)	NR	31 $\pm$ 30	36 $\pm$ 33	21 $\pm$ 30	Added five questions; occupational subscore: 13 $\pm$ 26
Zug (this study)	—	Patients referred for patch testing (107)	59 $\pm$ 25*	60 $\pm$ 27	67 $\pm$ 27	43 $\pm$ 31	Added five occupational questions to Skindex-16; occupational subscore: 22 $\pm$ 27

NR = not reported; QoL = quality of life.

*Global QoL was calculated by omitting the occupational domain for comparison with other reported global QoLs.

previously had scores indicating a better QoL. As we found in our study, Kadyk and colleagues found the greatest impact (ie, the worst QoL scores) on emotions, followed by symptoms, functioning, and occupational impact. Patients with hand dermatitis had significantly worse QoL occupational and functioning scores on all items. As in our study, younger patients in the study by Kadyk and colleagues tended to have worse QoL scores.¹²

Another QoL tool used clinically is the Dermatology Life Quality Index (DLQI), whose assessment categories divide the effect of a skin condition into ten questions pertaining to the following six domains: (1) symptoms and feelings, (2) daily activities, (3) leisure activities, (4) work/school activities, (5) personal relationships, and (6) treatment. Holness used the DLQI to evaluate QoL in a patch-tested population and found that embarrassment, work interference, pain, itching, and sleep difficulties were the most significant effects.⁶ Unlike Skindex-16, the DLQI questionnaire does not have a scale for frustration, annoyance, and bother by persistence of the condition.

Woo and colleagues assessed the effect of patch testing on QoL in a prospective study with 6 weeks of follow-up, also using the DLQI.¹¹ They reported that contact dermatitis had a marked effect on QoL; patients with a final diagnosis of allergic contact dermatitis had a mean baseline DLQI score equal to that of patients experiencing hair loss and psoriasis. Baseline DLQI scores indicated a worse QoL for patients with dermatitis involving the trunk, unlike our study, in which the hand was the only site associated with a statistically significant difference in QoL score. Improved QoL in the 6 weeks after patch testing was found both for patients with positive patch-test results and for patients with negative patch-test results.

Factors Predictive of a Negative Impact on QoL

Our hypothesis that hand involvement would be associated with worse Skindex-16 QoL scores was correct. Hand eczema is known to affect QoL as measured by the DLQI and by Short Form-36 (SF-36), a health-related QoL tool.¹³ Wallenhammer and colleagues used SF-36 and found some gender differences in mental health among patients with hand eczema, women being more affected than men. The same investigators did not detect this when studying the same population with the DLQI (for 100 patients). Using the DLQI and the Beck Depression Inventory (BDI-II), Cvetkovski studied newly recognized cases of hand dermatitis in Danish workers identified by the National Board of Industrial Injuries; baseline values indicated the most severe impact on symptoms, feelings,

and work/school. No significant differences in QoL were reported for gender, age, disease duration, diagnosis, or occupation. Severity of occupational hand eczema was strongly associated with QoL at baseline.¹⁴ Other studies cited female sex as associated with lower QoL scores as measured by Skindex-16.^{15,16}

Table 5 compares Skindex-16 scores among a number of studies assessing different diseases. Notably, the effect on emotions in our patch-test patients as a whole (67) was comparable to that reported by Chren and colleagues in psoriasis patients (68)¹⁰ and by Kawashima and Harada in patients with atopic dermatitis (68).¹⁷

Limitations

This pilot study had several limitations. First, patients undergoing patch testing at this referral center are not necessarily reflective of all patients who undergo patch testing. Many patients evaluated at our center tend to have had a lengthy disease duration and a challenging dermatitis in terms of disease extent and previous unsatisfactory treatment response. The population was also heterogeneous—these patients were not solely patients with allergic contact dermatitis or relevant positive patch-test results. Second, this was a convenience sample; although we did not intend to select patients to complete the survey, there may have been some unintended selection bias. Third, we may not have had the power to detect important variables that affect QoL, such as relationship to occupation, facial involvement, or scattered or generalized involvement. Finally, the survey questions regarding occupational impact have not been validated.

Conclusion

This population of patients presenting for expanded allergen patch testing at a referral center were most bothered by symptoms of itching and irritation. The emotional scale of the Skindex-16+5 questionnaire confirmed that this group of patients were severely affected by frustration; they reported feeling annoyed and had great concern about the persistence of their skin problem. Hand involvement was the most important predictor of a poor quality of life (QoL) for these patients and was the only variable associated with a significant occupational QoL impact. Owing to Health Insurance Portability and Accountability Act (HIPAA) regulations and our initial study design, we were unable to follow up these patients to assess for changes in QoL after their visit for patch testing.

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