Validating Responsiveness of a Quality-of-Life Instrument for Allergic Contact Dermatitis

Jodie Raffi, BA, MD,*† Isabel Elaine Allen, PhD,‡ and Nina Botto, MD*

Background: **Although many generic dermatological quality-of-life (QoL) instruments exist, none have been specifically designed for patients with allergic contact dermatitis (ACD). In the preceding publication—Validating a Quality-of-Life Instrument for Allergic Contact Dermatitis—we developed and validated a QoL instrument specific to the ACD population.**

Objective: **The aim of this study was to assess whether this ACD-specific QoL instrument appropriately captures change in QoL after patch testing in ACD patients.**

Methods: **One hundred individuals completed the previously validated 17-item QoL survey plus 2 global questions and the Skindex-29 before patch testing. Two months after patch testing and allergen avoidance, the participants repeated the same questionnaires. We used statistical methods to evaluate the capacity of the ACD questionnaire to measure change in QoL in comparison with the Skindex-29.**

Conclusions: **The novel ACD-specific questionnaire was more sensitive to change in QoL than the generic Skindex-29. Eleven of the original 17 items were found to capture change in QoL, and of the 3 domains (emotions, symptoms, functioning), the emotional aspect of the disease was most burdensome and responsive to change 2 months after patch testing. Providers can reliably use this index to assess changes in QoL over time.**

Allergic contact dermatitis (ACD) affects a substantial portion of the population, but there is no consensus as to which standardized instruments are most useful in assessing the burden of ACD on quality of life (QoL). The Dermatology Life Quality Index (DLQI), the Skindex, and the Dermatology-Specific Quality of Life instrument have been the most commonly used QoL instruments by dermatologists. However, as detailed by Ramirez et al,[1] these QoL instruments lack either clinical applicability or proper validation in the ACD population. For this reason, we developed and validated a QoL instrument specifically for individuals with ACD, as previously published.[2]

Of the few studies investigating the effect of patch testing on QoL in ACD, there is evidence to suggest that patch testing does improve QoL in individuals with ACD.[1,3–5] However, there have been no prospective studies using an ACD-specific QoL tool to evaluate the effect of dermatologist-managed ACD on QoL.

In a previous publication, we describe the creation and validation of a comprehensive, disease-specific QoL instrument for individuals with ACD.[2] The objective of the present study was to assess whether this ACD-specific QoL instrument appropriately captures changes in QoL after patch testing in ACD patients. Furthermore, we aimed to determine whether our hypothesis that patch testing and subsequent allergen avoidance, the mainstay interventions for ACD, do lead to an improvement in QoL over time is correct.

METHODS

We hypothesized that our ACD-specific tool would measure a change in QoL before and after patch testing and that an improvement in QoL after patch testing would be observed.

Sample Population

Participants in this study were recruited from the University of California, San Francisco (UCSF) Patch Test Clinic and comprised a distinct population from that included in the validation study. All patients gave consent for participation. This study was approved by the UCSF institutional review board committee.

There were 160 total patients referred to UCSF Dermatology for patch testing from May 2017 to July 2018. Among these patients, 60 were excluded from the study because of a lack of clinically relevant patch test reactions or being non–English speaking, younger than 18 years, or unwilling to participate in the study. For the remaining 100 patients who met the inclusion criteria, 48 completed the study questionnaires. Responses from these 48 patients were used in our analyses.

*From the *Department of Dermatology, University of California, San Francisco; †University of California, Irvine School of Medicine; and ‡Department of Epidemiology and Biostatistics, University of California, San Francisco.*

Address reprint requests to Nina Botto, MD, Department of Dermatology, University of California, San Francisco, 1701 Divisadero St, San Francisco, CA 94115. E-mail: nina.botto@ucsf.edu.

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Patch Testing Procedure

All patients were tested with the American Contact Dermatitis Society Core 80 Allergen Series[5] and additional series as needed based on history and clinical context. Allergens were obtained from Dormer, a North American provider of allergens manufactured by Chemotechnique Diagnostics (Vellinge, Sweden), and allerGEAZE (SmartPractice, Calgary, Alberta, Canada). Patch tests were applied with Finn Chambers (SmartPractice, Phoenix, AZ) on Scanpor tape (Norgesplaster Alpharma AS, Vennesla, Norway).

Data Collection: Patch Testing and QoL Questionnaires

To understand the responsiveness of our 17-item ACD-specific survey[2] to change in QoL, we compared it with the Skindex-29. Answer choices to both the Skindex-29 and ACD questionnaire are on a 5-element Likert scale ranging from "never" to "all the time," where a higher score indicates a poorer QoL. Similar to the Skindex-29, our ACD-specific questionnaire and the global questions (GQs) inquired about the past 4 weeks. We administered 2 "GQs" with the ACD instrument as a method of understanding patients' sense of their own disease severity and QoL. The 2 GQs are as follows: "Overall, how would you describe the severity of your skin condition?" and "Overall, how would you describe the effects of your skin condition on your quality of life?" Answer choices are on a 5-element Likert scale including "none," "mild," "moderate," "severe," and "very severe." Demographics were collected according to the MOAHFLA index (male, occupational dermatitis, atopic dermatitis, hand, face, leg, age >40 years index).[6] The effect of sex, age group, and atopic versus occupational dermatitis on the ACD survey and the Skindex-29 was evaluated with 1-way analysis of variance.

We administered the novel 17-item ACD instrument plus the 2 GQs combined with the Skindex-29 for comprehensive disease assessment to establish a baseline QoL. Patients answered all questions on a paper questionnaire at the initial visit. Two months after patch testing and allergen avoidance counseling, participants were invited to complete the same questions electronically to assess current QoL and change from baseline.

Statistical Methodology

We evaluated the responsiveness of the ACD-specific questionnaire to changes in QoL at the time of patch testing and 2 months after; we also compared the change measured by the ACD questionnaire with that by the Skindex-29 at these 2 time points. We compared participants' responses to individual questions on each of the ACD questionnaire and Skindex-29 at time 0- and 2-month follow-up after patch testing using paired *t* tests adjusted for multiple comparisons.

The following 3 subscales, or domains of questions, were identified in the ACD-specific questionnaire: symptoms, emotions, and functioning.[4] Responses grouped by the 3 domains within both the ACD questionnaire and Skindex-29 instrument were compared at time 0 and at 2 months after patch testing using paired *t* tests. Results in the individual patient analyses used the false discovery rate method to control for multiple comparisons. This method calculates the *P* value needed for significance when examining multiple tests on the same data.

Percent changes in response to the subscale questions between pre– and post–patch test questionnaire administrations were then calculated for the ACD questionnaire and the Skindex-29, for the group as a whole. The percent of scores showing an improvement in the ACD questionnaire was compared with that of the Skindex-29 using a χ^2 test.

All analyses used $P < 0.05$ as the criterion for statistical significance before multiple-comparisons adjustment. Stata v.15.1 (StataCorp, College Station, TX) and SPSS v.25 (IBM Corp, Chicago, IL) were used for all statistical analyses.

RESULTS

A total of 100 patients were enrolled in the study, as they met the qualifications, completed the initial questionnaire, and underwent patch testing. All 100 of these individuals had relevant positive results on patch testing; patients were counseled regarding avoidance of these allergens. After 2 months, 48 (48%) completed the second administration ACD questionnaire and Skindex-29. Fifty-two individuals did not return the follow-up survey and were not included in the data analysis. Demographic information according to the MOAHFLA index is presented in Table 1. Most participants were female (n = 34) and had nonoccupational dermatitis (n = 42). Nearly half of the participants had atopic dermatitis as an additional diagnosis (n = 23). The face was the most commonly affected area (n = 33). Statistical analysis yielded no significant differences between demographic variables (sex, age group, atopic vs occupational dermatitis) and pre– or post–patch test scores on the final ACD questionnaire, the Skindex-29, or their respective subscales. The location of dermatitis could not be analyzed because of small sample sizes.

All patients received detailed counseling and allergen avoidance information regarding allergens discovered on patch testing. Counseling included written information on allergen profiles and a list of safe,

TABLE 1. The MOAHFLA*[6] Characteristics of Participants Who Responded to Both Pre– and Post–Patch Testing Questionnaires

Characteristic	n (%)
Male	14 (29.2)
Occupational	6 (12.5)
Atopic dermatitis	25 (52.1)
Age >40 y	23 (47.9)
Hand†	13 (27.1)
Leg†	10 (20.8)
Face†	33 (68.8)
Positivity rate (>1 allergic reactions)	39 (81)

**MOAHFLA, male, occupational dermatitis, atopic dermatitis, older than 40 years, hand, legs, face (including lips, eyes, and eyelids), and positivity rate on patch testing.*
†Primary site of ACD.

allergen-free products to use. Personal products were also reviewed in detail for all patients, when possible, to identify culprit allergens at the time of final reading. Patients were encouraged to follow up in clinic after 2 months.

Novel Tool Compared With Skindex-29

When comparing responses with individual questions on the ACD questionnaire at baseline and 2-month follow-up, statistically significant change was observed longitudinally in 11 of the 17 items with the paired *t* test, with adjustment for multiple comparisons (Table 2). The questionnaire was thus shortened to include the 11 items that captured responsiveness to change in QoL and renamed the "ACD-11."

The overall percent of patients showing improvement after patch testing—among those who improved on the GQs—was significantly higher with the ACD-11 than the Skindex-29. Specifically, the ACD-11 demonstrated 8% more improvement in scores than Skindex-29 scores ($P = 0.047$).

In addition, the ACD-11 measured greater improvement than the Skindex-29 ($P = 0.050$) using a χ^2 test comparing percent improvement. A significantly larger percent of individual questions on the ACD-11 indicated improvement after patch testing compared with the Skindex-29. For those who indicated improvement on the GQs, only 11 (38%) of 29 Skindex-29 questions indicated improvement, whereas 8 (73%) of the final 11 ACD questions measured improvement. When analyzed by domain, the ACD-11 demonstrates significant improvement with respect to emotions and symptoms. The Skindex-29 did not show significant improvement in any of the 3 domains (Table 3).

The Effect of Patch Testing and Allergen Avoidance on QoL in Patch Test–Positive Patients

Based on responses to the GQs, 60% of study participants reported improvement in QoL after patch testing, as evidenced by selection of a less severe Likert category on the post–patch test questionnaire. Of those who indicated an improvement in QoL on the GQs, their corresponding ACD-11 results showed emotions and symptoms to be the most significantly improved. Sixty-three percent of patients reported reduction in disease severity after patch testing. Of those who experienced reduction of disease severity after patch testing, significant change on the ACD-11 was seen with questions in all 3 domains.

Overall improvement in QoL after patch testing was demonstrated by an increase in number of patients selecting "mild" on the GQs and a decrease in respondents in the moderate, severe, and very severe categories (Table 4). Responses of increasing severity on the GQs correlated linearly with increasing average ACD score, indicating that the GQs and ACD-11 align in their assessment of QoL.

DISCUSSION

This study demonstrates the responsiveness of a QoL tool developed specifically for individuals with ACD. This ACD-specific tool was found to be responsive to change in QoL after patch testing, as evidenced by statistically significant change in responses to individual questions before and after patch testing. Furthermore, because only 11 of the original 17 items were found to be responsive to change in QoL, the final tool was shortened to 11 items, and accordingly, we call this questionnaire the "ACD-11."

Counseling on allergy avoidance in patch test–positive patients resulted in improvement in QoL on both the ACD-11 and Skindex-29, which is consistent with not only our experience as clinicians but also other reports in the literature.[4,7,8] Compared with the Skindex-29, the ACD-11 was more responsive to change in QoL after patch testing. This was demonstrated by a greater proportion of questions recording improvement and a larger amount of improvement overall measured by the ACD questionnaire compared with the Skindex-29. It is not surprising to us that a disease-specific tool may be better able to measure change in QoL than a generic instrument, as it was designed specifically to capture the most distressing elements of the disease. Accordingly, the ACD-11 measured change in the emotions and symptoms domain with greater significance than the Skindex-29 (Table 3). The disease-specific tool provides greater focus on the particular clinical and psychosocial factors specific to ACD rather than skin disease in general.

We found the overall emotional impact of ACD to be the most burdensome and responsive to change in our patients. The improvement in emotional factors after patch testing was evidenced by significant reductions in mean scores to ACD-11 questions, such as "My skin condition makes it hard to concentrate or focus" and "My skin condition makes me feel out of control." Patch testing and allergen avoidance also led to improvement in the physical aspects (symptoms domain) of the disease, evidenced by improvements in items, such as "I am bothered by the cracking in my skin," "I am bothered by sloughing and flaking from my skin condition," "I am bothered by peeling from my skin condition," and "I am bothered by the appearance of my skin condition." The functioning domain was the least responsive to change in ACD patients on the ACD-11; this scale seemed to be the least predominant in qualitative interviews of ACD patients[4] and thus is composed of the fewest items on the ACD-11. In addition, a smaller component of the participant group experienced hand dermatitis, which directly and physically interferes with activities of daily life, compared with facial dermatitis, which is more likely to be emotionally distressing. It may also be that these items are simply less responsive to change in the ACD patient or that they are not as relevant to the disease compared with the emotions and symptoms scales.

When looking at individual items on the Skindex-29, the greatest change after patch testing was seen with items referring to itch and irritation, as well as the annoyance and frustration associated with the skin condition. In keeping with this, the individual symptoms items in the ACD-11 showed the greatest change. This suggests that physical symptoms may be most notably improved at initial follow-up (2 months). Interestingly, the individual emotional items most improved after patch testing on the Skindex-29, annoyance and frustration, may reflect more transient day-to-day emotions,

TABLE 2. Novel ACD Instrument and Skindex-29: Question Items and Response to Change

	Domain	Mean Improvement	SD	*P*
ACD instrument items*				
1. My skin condition makes it hard to concentrate or focus.	Functioning	0.500	0.899	0.000
2. I think about my skin condition all the time.	Functioning	0.350	1.139	0.036
3. My skin condition makes me feel desperate.	Emotions	0.330	0.996	0.025
4. I am bothered that my skin condition never goes away.	Emotions	0.420	1.397	0.044
5. I am worried because my skin condition is unpredictable.	Emotions	0.480	1.220	0.009
6. My skin condition makes me feel out of control.	Emotions	0.560	1.090	0.001
7. I worry about being exposed to things that make my condition worse (eg, trigger).	Emotions	0.330	1.078	0.037
8. I am bothered by cracking in my skin.	Symptoms	0.730	1.162	0.000
9. I am bothered by sloughing and flaking from my skin condition.	Symptoms	0.810	1.085	0.000
10. I am bothered by peeling from my skin condition.	Symptoms	0.670	0.996	0.000
11. I am bothered by the appearance of my skin condition.	Symptoms	0.580	1.235	0.002
12. My skin condition makes me feel “high maintenance” (eg, have to use special products).	Emotions	0.000	1.203	1.000
13. I am worried about infecting other people.	Emotions	0.000	1.203	1.000
14. My skin condition makes me feel crazy or neurotic.	Emotions	0.000	1.203	1.000
15. My skin condition makes me feel hopeless.	Emotions	0.000	1.203	1.000
16. My skin condition makes me feel dirty.	Emotions	0.000	1.203	1.000
17. My skin condition makes it hard to use my hands.	Functioning	0.000	1.203	1.000
GQs†				
1. Overall how would you describe the severity of your skin condition? (none, mild, moderate, severe, extremely severe)	NA	0.85	1.031	<0.001
2. Overall how would you describe the effects of your skin condition on your quality of life? (none, mild, moderate, severe, extremely severe)	NA	0.88	1.231	<0.001
Skindex-29 items*				
1. My skin condition affects my interactions with others.	Functioning	0.580	1.164	0.001
2. I tend to do things by myself because of my skin condition.	Functioning	0.380	0.733	0.001
3. My skin condition is a problem for the people I love.	Functioning	0.380	0.981	0.011
4. My skin condition interferes with my sex life.	Functioning	0.230	1.259	0.213
5. My skin condition affects how well I sleep.	Functioning	0.810	1.003	<0.002
6. My skin condition affects my social life.	Functioning	0.710	0.824	<0.001
7. My skin condition makes showing affection difficult.	Functioning	0.380	1.024	0.015
8. My skin condition affects my desire to be with people.	Functioning	0.350	0.934	0.012
9. My skin condition makes it hard to work or do hobbies.	Functioning	0.480	1.288	0.013
10. My skin condition affects how close I can be with those I love.	Functioning	0.480	1.091	0.004
11. My skin condition burns or stings.	Functioning	0.750	1.263	<0.001
12. I tend to stay at home because of my skin condition.	Functioning	0.380	0.981	0.011
13. I worry about getting scars from my skin condition.	Emotions	0.480	0.825	<0.001
14. I worry that my skin condition may be serious.	Emotions	0.600	0.818	<0.003
15. My skin condition makes me feel depressed.	Emotions	0.460	0.849	0.001
16. I am annoyed by my skin condition.	Emotions	0.980	1.021	<0.001
17. I am humiliated by my skin condition.	Emotions	0.250	0.911	0.063
18. I am ashamed of my skin condition.	Emotions	0.560	1.090	0.001
19. I worry that my skin condition may get worse.	Emotions	0.630	1.024	<0.001
20. I am angry about my skin condition.	Emotions	0.460	1.091	0.005
21. I am frustrated by my skin condition.	Emotions	0.880	0.959	<0.001
22. I worry about side effects from skin medications/treatments.	Emotions	0.670	1.310	0.001
23. I am embarrassed by my condition.	Emotions	0.710	1.031	<0.001
24. My skin is sensitive.	Symptoms	0.460	1.091	0.005
25. My skin is irritated.	Symptoms	0.750	1.062	<0.001
26. My skin condition bleeds	Symptoms	0.420	0.895	0.002

(Continued on next page)

TABLE 2. *(Continued)*

	Domain	Mean Improvement	SD	*P*
27. My skin hurts.	Symptoms	0.810	1.161	<0.001
28. Water bothers my skin condition (bathing, washing hands).	Symptoms	0.230	1.207	0.195
29. My skin itches.	Symptoms	0.730	1.067	<0.001

Mean change and SD to the novel ACD instrument and Skindex-29 at 2-month follow-up. (Note: The 11 items comprising the final ACD-11 tool are represented as the first 11 items of the table. The remaining 6 items are not included in the final instrument but are presented here for analysis.)

**Scored on a Likert scale ranging from 1 to 5 (1, never; 2, rarely; 3, sometimes; 4, often; 5, all the time).*

†Scored on a Likert scale ranging from 1 to 5 (1, none; 2, mild; 3, moderate; 4, severe; 5, very severe).

contributing to early improvement, rather than the deeper attitudes and emotions conveyed by other emotional items included in the ACD-11 (such as feeling lack of control and desperation). Functional factors, such as the effect of ACD on sleep quality, also saw significant change on the Skindex-29 after patch testing, which may be related to more rapid physical improvement in areas such as itch and irritation, which affect sleep. This improvement was notable given that sleep did not seem to have a significant impact on QoL at baseline.[2]

Similar to other studies, our instrument found patch testing and allergen avoidance to improve QoL in individuals with ACD.[3,4,8] Thomson et al[4] performed a prospective analysis of patch testing on QoL using the DLQI and Short Form 36, both of which have been validated for use in atopic dermatitis, but not in ACD, and found significant improvement in QoL in patients with active eczema using the DLQI. The Short Form 36, which was not designed specifically to assess QoL in ACD, measured improvement (of borderline significance) only with regard to pain and no significant improvement with respect to the physical, vitality, social, emotional, and mental domains. Notably, our instrument, which was developed through qualitative interviews of patients with diagnosed ACD, did not identify pain as central to ACD.

The ACD-11 provides a comprehensive yet relatively quick assessment of QoL in patients with ACD. The 11-item questionnaire takes less than 2 minutes to complete and can be easily administered before or during a patient visit. In comparison, the 29-item Skindex-29 often takes approximately 5 to 6 minutes to complete. Similar to the Skindex-29, the ACD-11 queries patients about the following 3 domains of disease: emotions, symptoms, and functioning.[2,9] The questionnaire not only provides both a score indicating quantitative effect on QoL but also provides details regarding which aspects of the disease are most troublesome to the patient. As an instrument that is responsive to change, this questionnaire can be used across multiple visits, before and after patch testing, to evaluate a patient's current QoL and track improvement with diagnostic patch testing and allergen avoidance.

There are several limitations to this study. First, this study was performed at a single location, in a tertiary referral center in San Francisco, CA. Non-English speakers were excluded from the study, to ensure adequate understanding when developing and testing the tool. Second, only adults 18 years or older were included in this study, and thus, the instrument has not been validated in children. Third, our population was small (48 subjects) and heterogenous, and our referral patients often have more than 1 dermatologic diagnosis other than ACD and may have confused these in their responses. Fourth, we did not evaluate patch test–positive and patch test–negative individuals separately in this study. Finally, the relatively short follow-up period does not provide information on the long-term trajectory of the emotional aspects of QoL identified.

CONCLUSIONS

The ACD-11 is a validated, disease-specific, responsive QoL tool. It is more sensitive when compared with the generic Skindex-29 in

TABLE 3. Paired Mean Scores by Domain for Each QoL Tool

	Before Patch Testing	After Patch Testing	*P*
ACD-11 symptoms factor	13.60	10.75	<0.002
ACD-11 emotions factor	29.83	26.13	<0.002
ACD-11 functioning factor	2.50	2.42	0.083
Skindex-29 symptoms factor	21.62	17.48	0.021
Skindex-29 emotions factor	30.44	24.06	0.011
Skindex-29 functioning factor	25.73	20.29	0.099

TABLE 4. The ACD-11 Score by GQ Category, Before and After Patch Testing

	ACD-11 Score	
Response	Before Patch Testing	After Patch Testing
GQ 1*		
Mild	21.8 (6)	23.9 (26)
Moderate	30.6 (25)	27.6 (14)
Severe	36.5 (10)	33.8 (4)
Very severe	43.7 (3)	24.0 (1)
Total	31.7 (44)	25.9 (45)
GQ 2†		
Mild	19.6 (7)	15.3 (4)
Moderate	31.3 (23)	22.8 (20)
Severe	37.2 (10)	29.6 (17)
Very severe	41.0 (4)	34.8 (5)
Total	31.7 (44)	26 (46)

Data are presented as mean (n). Note: The mean ACD-11 score rises linearly with increasing severity of GQ Likert category.

**GQ 1: Overall how would you describe the severity of your skin condition?*

†GQ 2: Overall how would you describe the effects of your skin condition on your quality of life?

assessing patients with ACD. The ACD-11 allows clinicians to understand unique QoL items in ACD patients and characterize their clinical trajectory as well as the effect of clinical interventions in this patient population over time.

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