

Health-Related Quality-of-Life Assessment in Patients With Cutaneous T-Cell Lymphoma

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Objective: To measure and evaluate the health-related quality of life (HRQOL) in patients with cutaneous T-cell lymphoma (CTCL), a visible cutaneous malignancy that may have a profound effect on patients' lives.

Design: Monocenter, cross-sectional study.

Setting: The Skin Oncology Program, Department of Dermatology, and the Photopheresis Unit of Boston Medical Center.

Patients: A total of 22 adult patients with confirmed CTCL.

Main Outcome Measures: (1) Evaluation of general oncologic and skin disease-specific HRQOL using, respectively, the Functional Assessment of Cancer Therapy-General (FACT-G) and Skindex-29 profiles; (2) assess-

ment of HRQOL association with disease stage (early stage, IA-IIA; late stage, IIB-IVB).

Results: Patients with more advanced CTCL stages reported more effects on general health (FACT-G), particularly in the physical, emotional, and functional domains ($P < .05$). Patients with early-stage CTCL reported better skin-specific HRQOL overall (Skindex-29; $P = .002$) and for each specific domain than did patients with late-stage disease. The Skindex-29 scales had high internal consistency, and the confirmatory factor structure was similar to that of previous studies.

Conclusions: The HRQOL of patients with CTCL can be evaluated using the Skindex-29 and FACT-G instruments. Patients with more advanced stages of CTCL had lower HRQOL scores.

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CUTANEOUS T-CELL LYMPHOMA (CTCL) is a visible cutaneous malignancy that can cause significant morbidity and disfigurement and adversely affect patients' quality of life (QOL).¹ The most common type of primary skin lymphoma, CTCL has an estimated incidence of about 0.5 to 1 case per 100 000.² The most common forms, mycosis fungoides and its leukemic phase, Sézary syndrome, are generally chronic diseases. However, there is little available information on the experience of patients with mycosis fungoides or Sézary syndrome and how discrete aspects of their lives are affected by the disease.

cal, functional, psychological, and social health and well-being of the individual.^{4,7-9} Several therapies are currently being investigated for CTCL,¹⁰⁻¹² and so understanding the impact of CTCL and its treatments on patients' HRQOL has become important.¹ Nonetheless, only a limited number of general HRQOL questionnaires have been used for CTCL, and no disease-specific HRQOL questionnaires have emerged to evaluate patients with CTCL. To evaluate the extent of CTCL and stage of disease on patients' HRQOL, we used 2 existing instruments: a general oncology HRQOL instrument, the Functional Assessment of Cancer Therapy-General (FACT-G),¹³ and a skin disease-specific HRQOL instrument, Skindex-29.¹⁴

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See also pages 305, 353, 361, 395, and 382

Patients' perceptions of their health-related QOL (HRQOL) have become important measures of case mix and outcomes in dermatology and oncology.³⁻⁶ Health-related QOL is a multidimensional construct that includes the physi-

METHODS

PATIENT SAMPLES

Informed consent was obtained from 22 adult patients with a confirmed diagnosis of mycosis fungoides or Sézary syndrome. The study was approved by the institutional review board of Boston Medical Center. The sample included 10 patients with early-stage (IA-IIA) and 12 with late-stage (IIB-IVB) CTCL who were

Table 1. Patient Demographic and Disease Characteristics

Characteristic	No. of Patients* (N = 22)
Sex	
Male	11
Female	11
Ethnicity	
White	20
African American	1
Asian	1
Disease stage	
IA-IIA	10
IIB-IVA	12
IVB	0
No. of comorbidities	
0	6
1	2
2	7
>3	7

*Mean patient age, 63.1 years; age range, 32 to 81 years.

Table 2. Prior Therapies Received by Study Patients*

No. of Prior Therapies	No. of Patients	Type of Therapy†	
		Topical	Systemic
1	6	X	None
2	3	XX	None
	1	X	X
3	4	X	XX
	2	XX	X
4	1	X	XXX
≥5	1	XXX	XX
	2	XX	XXX
	2	X	XXXX

*Prior topical therapies included steroids, chemotherapy, and bexarotene; prior systemic therapies included phototherapy (UV-B, narrowband UV-B, and psoralen plus UV-A), local radiation, total skin electron beam radiation, oral bexarotene, subcutaneous interferon alfa, subcutaneous interleukin 2, and extracorporeal photopheresis.

†Each X indicates 1 therapy.

referred to the Skin Oncology Program clinic or were undergoing treatment at Boston Medical Center for their disease. Demographic information, stage of disease, number of prior treatments, and number of comorbidities were recorded. Patients completed the questionnaires during their evaluation in the clinic or while undergoing treatment at Boston Medical Center.

HRQOL EVALUATION

General oncologic-specific HRQOL was measured using the FACT-G, version 4, a self-administered, 27-item questionnaire¹³ that has been used widely and is available in more than 40 languages. Through ongoing validation studies, the FACT-G has demonstrated sound psychometric properties to support its usefulness in evaluating HRQOL in cancer populations.^{13,15,16} It was chosen based on its prior successful use in studies of CTCL¹⁷ and other malignancies.^{18,19} The FACT-G instrument assesses 4 HRQOL domains: physical well-being (7 items); social and/or family well-being (7 items); emotional well-being (6 items); and functional well-being (7 items). Respon-

dents use a 5-point Likert-type scale that rates the relevant domain from 0 (not at all) to 4 (very much). Possible scale scores (the sum of responses to the items included in the scale) range from 0 to 108, with a higher score indicating better HRQOL. The FACT-G has demonstrated both discriminant and convergent validity, with test-retest correlations ranging from 0.82 to 0.92 for each FACT-G subscale. The FACT-G can be completed in 5 to 10 minutes.²⁰

Skin disease-specific HRQOL was measured using the Skindex-29, a validated, self-administered, 29-item questionnaire.²¹ Results of the Skindex-29 are reported as 3 scale scores assessing emotions, physical symptoms, and functioning. Scale scores are the means of responses to the items included in the scale. Possible scale scores range from 29 to 116. Higher scores indicate worse HRQOL. The Skindex-29 has demonstrated both discriminant and convergent validity with test-retest correlation ranging from 0.88 to 0.92. Completion of the Skindex-29 takes 5 minutes.²¹ Scoring of FACT-G and Skindex-29 scales was performed as previously described.^{13,22}

STATISTICAL ANALYSIS

Scale scores computed for each patient were summarized as means (SDs) overall and in subsets of patients defined by sex, age, and stage of disease. Differences between groups were tested using *t* tests and general linear regression. Psychometric properties of the questionnaires were evaluated using confirmatory factor analysis, with matrix structures specified based on previously published reports.^{13,14} Confirmation was based on loading of individual items to prescribed factors. Higher factor loading scores indicate that item responses are more strongly correlated with other items in the factor. For presentation purposes, score values were multiplied by 100, and a minimum value of 50 was used as the criterion of significance. This analysis was conducted using Proc Calis in SAS 8.2 (SAS Institute Inc, Cary, NC). Internal consistency reliability of scales was assessed using Cronbach α coefficients.

RESULTS

The 22 patients with CTCL ranged in age from 32 to 81 years (mean age, 63.1 years) (**Table 1**). There were equal numbers of male and female patients, and most were white. All patients had received prior treatment (mean number of prior therapies, 2.5; **Table 2**). Sixteen (73%) of the patients had at least 1 comorbidity. Common comorbidities included coronary artery disease, hypertension, hypercholesterolemia, diabetes, and peripheral vascular disease; less common comorbidities included history of uterine cancer, erectile dysfunction, urinary incontinence, osteoarthritis, congenital optical blindness, B-cell chronic lymphocytic leukemia, and nonmelanoma skin cancers.

The FACT-G mean scale scores for patients with CTCL are listed in **Table 3**. Mean (SD) scores ranged from 17.9 (5.9) to 22.7 (5.7). For comparison purposes, Table 3 also includes published FACT-G mean scale scores for patients with nonmelanoma cervicofacial skin cancer (NMSC).¹⁹ For all 4 scales, mean scores were lower in our patients with CTCL.

Skindex-29 mean scale scores for patients with CTCL are listed in **Table 4**. Mean scale scores ranged from 19.1 to 24.2, indicating some effects of the skin disease on HRQOL.

EFFECTS OF EARLY- VS LATE-STAGE CTCL ON HRQOL

Patients with late-stage CTCL (IIB-IVA) reported lower FACT-G scores than patients with early-stage disease (IA-IIA) overall and across all domains (**Table 5**). Statistically significant differences ($P < .05$) were observed for all individual scales except social/family well-being.

Similar results were found for Skindex-29. Patients with late-stage CTCL had significantly higher (worse) mean scores overall and across all scales than did patients with early-stage disease.

PSYCHOMETRIC ANALYSIS

The results from confirmatory factor analysis of the Skindex-29 are listed in **Table 6**. Most items loaded appropriately to the 3 scales (emotions, symptoms, and functioning) previously defined and described.¹⁴ In only a few instances were factor-loading scores in a scale lower than 50 (eg, “worry about getting scars” failed to load on the emotions scale as expected but loaded on functioning instead) or were items split between scales with factor-loading scores higher than 50 for 2 factors (eg, “condition affects my desire to be with people” loaded on both the emotions and functioning scales). Otherwise, items loaded appropriately, and the questionnaire appeared to provide reliable measures of emotional, symptomatic, and functional domains of HRQOL in patients with CTCL. The internal consistency reliability of the scales as indicated by the Cronbach α coefficients ranged from 0.89 to 0.95.

COMMENT

Cutaneous T-cell lymphoma is a disease with visible manifestations that may include patches, plaques, tumors, hair loss, keratoderma, fissures, and symptoms of pruritus and pain. These signs, as well as an increasing risk of death with worsening stage, would be expected to have important effects on patients' QOL. This includes effects on emotions (eg, fear of death, embarrassment from skin condition, anger, frustration), physical functioning (eg, ability to work or do hobbies), and social well-being (eg, ability to interact with others or desire to be with others). Even without increased mortality risk, patients with the earliest stage of CTCL, stage IA, might have impaired HRQOL. For example, a patient with stage IA disease commented on how the visible nature of the skin lesions prevented her from going to the beach with her family. These and other impairments in HRQOL would be expected to increase with increasing stage of disease.

In our study, we examined general oncologic health and skin-specific HRQOL in a representative sample of patients with CTCL seen at our center. We found relatively poor HRQOL associated with the disease, with the lowest levels in patients with the most advanced disease.

Patients with CTCL reported low scale scores (impaired HRQOL) in all 4 FACT-G subscales (physical, social/family, emotional, and functional well-being). These

Table 3. Comparison of FACT-G Results for 22 Patients With CTCL From the Present Study and an Earlier Cohort With NCSC

Well-being Domain	Mean (SD) Score	
	CTCL	NCSC*
Physical	22.7 (5.7)	26 (2.6)
Social/family	22.3 (4.9)	25 (3.8)
Emotional	17.9 (5.9)	20 (3.4)
Functional	19.0 (6.6)	24 (5.0)

Abbreviations: CTCL, cutaneous T-cell lymphoma; FACT-G, Functional Assessment of Cancer Therapy–General scale¹³; NCSC, nonmelanoma cervicofacial skin cancer.

*Data obtained from Rhee et al.¹⁹

Table 4. Skindex-29 Results for 22 Patients With CTCL

Domain	Mean (SD) Score	
	CTCL	Normative Sample*
Emotions	23.9 (8.9)	9.2 (12.8)
Symptoms	19.1 (7.2)	13.8 (11.9)
Functioning	24.2 (10.4)	3.7 (8.3)

Abbreviation: CTCL, cutaneous T-cell lymphoma.

*Data obtained from Figure 1 in Lasek and Chren.²³

values were lower than those reported by patients with high-risk NMSC.¹⁹ The population of 121 patients with high-risk NMSC (median age, 63 years) consisted of patients referred to a tertiary care surgery clinic for removal of a high-risk NMSC lesion (eg, tumor diameter, >2 cm; tumor of long duration; and/or tumor arising within the high-risk facial zone). Although variations in sociodemographic characteristics or comorbidities between the 2 patient groups may explain part or all of the observed differences, this finding suggests that patients with CTCL have relatively poor HRQOL, as measured with FACT-G.

For skin disease–specific HRQOL measured with Skindex-29, patients with CTCL reported decrements of HRQOL in all 3 dimensions (emotional, symptoms, and functioning). The observed mean scale scores (emotions, 23.9; symptoms, 19.1; and functioning, 24.2; Table 4) appear to be considerably higher than the published mean scale scores for 107 healthy volunteers who denied skin problems (emotions, 9.2; symptoms, 13.8; and functioning, 3.7).²³ Several studies have highlighted the impact of psoriasis on HRQOL.^{24,25} In the present study, overall, the impact of CTCL on functioning (mean scale score, 24) seemed to be similar to that reported for patients with psoriasis assessed with Skindex-29 (mean scale score, 23),²³ although the effect on emotions and symptoms well-being appeared to be somewhat less. However, part or all of these differences may be related to other differences between psoriasis and CTCL patient populations. For example, in the present study, the mean age of patients with CTCL was 63.1 years, considerably older than the mean age of 47 years reported in 1 series of patients with psoriasis.²⁶ Furthermore, QOL

Table 5. Health-Related Quality of Life Scores for 22 Patients With Early- vs Late-Stage CTCL*

HRQOL Instrument	Testing Domain									
	Physical	P Value†	Social/Family	P Value	Emotional	P Value	Functional	P Value	Total	P Value
All patients	22.7 (5.7)		22.3 (4.9)		17.9 (5.9)		19.0 (6.6)		82.0 (19.9)	
Patients with stage IA-IIA disease	25.4 (2.5)	.03	24.1 (3.8)	.10	21.6 (3.3)	.004	22.9 (4.2)	.007	94.1 (10.1)	.005
Patients with stage IIB-IVB disease	20.5 (6.7)		20.7 (5.3)		14.9 (6.0)		15.8 (6.6)		72.0 (20.7)	

Skindex-29	Symptom	P Value	No Analogous Domain	P Value	Emotions	P Value	Functioning	P Value	Total	P Value
Patients with stage IA-IIA disease	15.2 (6.6)	.02	NA	NA	18.1 (7.2)	.003	18.1 (7.5)	.007	51.4 (17.8)	.002
Patients with stage IIB-IVB disease	22.4 (6.2)		NA		28.7 (7.3)		29.3 (10.0)		80.4 (20.8)	

Abbreviations: FACT-G, Functional Assessment of Cancer Therapy–General; HRQOL, health-related quality of life; NA, not applicable.

*Unless otherwise indicated, data are presented as mean (SD) scores in the given HRQOL scale.

†All P values are determined by t test for difference by disease stage.

research in patients with psoriasis has indicated that younger age groups (<55 years) report a greater impact of psoriasis on the psychosocial aspects of their lives than do older age groups (≥55 years).²⁵ In addition to the age difference, the differences in Skindex-29 findings may be related to illness or socioeconomic factors in the 2 populations.

Health-related QOL was related to CTCL stage. The FACT-G scores were lower (worse) and Skindex-29 scores were higher (worse) in patients with late-stage disease than in those with early-stage disease. This was evident across all scales of the 2 instruments. These results are consistent with expectations in that patients with late-stage CTCL generally have more severe symptoms (eg, pruritus and pain) and face higher risks of debilitating disease and death than do patients with early-stage disease. This indicates face validity for both FACT-G and Skindex-29 measures and suggests that they are appropriate instruments for measuring HRQOL in CTCL. The completion time for the 2 questionnaires was not burdensome: it took no more than 15 minutes.²⁷

Skindex-29 showed good psychometric properties with high internal consistency, reliability, and factor structure, similar to its performance in previous reports.¹⁴ The few aberrant items that showed low factor-loading scores or that split between scales were questions that also showed the lowest scores in the published analyses. This questionnaire appears to measure emotional, symptomatic, and functional impacts of CTCL, as originally defined in the development of Skindex-29, with reasonably good accuracy and precision.

There are several limitations that should be kept in mind. This study was limited to a single tertiary referral center, and the results might not be generalizable to all patients with CTCL. In particular, our sample included mostly white patients, whereas the national data indicate a higher incidence rate among African Americans than among whites (1.6; 95% confidence interval, 1.3–1.8).²⁸

It is also possible that our patients with CTCL were referred to our tertiary referral center because they felt a

greater impact of CTCL on their HRQOL. Alternatively, since most of our patients completed the questionnaires either after their evaluation or during treatment, this timing might have minimized the impact on HRQOL, especially in those with early-stage disease vs more advanced disease (ie, those with a better prognosis may have been reassured by their visit or treatment) and thus magnified the difference between early-stage and late-stage disease. In addition, one cannot exclude the possibility that completing the HRQOL instruments after consultation in the Skin Oncology Program clinics or while receiving therapy influenced the responses of all patients, overall minimizing the impact of CTCL on their HRQOL. Future studies should ensure that the administration of questionnaires is done in a consistent manner, eg, prior to a clinic visit or to receiving therapy.

The sample size of only 22 patients was another limitation. A larger patient population involving multiple centers would provide a more representative sample to evaluate the impact of CTCL on HRQOL and increase power to detect differences.

Another limitation is that the study was cross-sectional. We evaluated QOL at only 1 time point. The study did not observe patients prospectively to evaluate disease impact on aspects of life over time. Future studies should evaluate responsiveness to change of both instruments in patients with CTCL.

We are aware of only 3 studies that have evaluated HRQOL of patients with CTCL (**Table 7**).^{17,29–32} The first study¹⁷ is a phase 3 study of denileukin diftitox (ONTAK; Ligand Pharmaceuticals, San Diego, Calif) in 71 patients with stage IB-IVA disease, where FACT-G (third version) was the only HRQOL instrument administered at baseline and after each course of therapy. The study showed a correlation between clinical response and improved HRQOL as measured by FACT-G. The second study, a multicenter study of oral bexarotene in 94 patients with stage IB-IVB disease, used the general status HRQOL questionnaire.²⁹ Baseline scores were reportedly high and did not substantially change during the study.^{30,31} In the third study, Bisaccia et al³² described the use of a 20-item, CTCL-

Table 6. Confirmatory Factor Analysis for Skindex-29 Among 22 Patients With CTCL

Confirmatory Factor Analysis	Emotions	Symptoms	Functioning
I worry that my skin condition may be serious.	56*	49	36
My skin condition makes me feel depressed.	77*	22	35
I worry about getting scars from my skin condition.	17	1	58*
I am ashamed of my skin condition.	76*	23	44
I worry that my skin condition may get worse.	82*	9	24
I am angry about my skin condition.	74*	12	41
I am embarrassed by my skin condition.	74*	15	49
I am frustrated by my skin condition.	81*	23	37
I am humiliated by my skin condition.	72*	21	42
I am annoyed by my skin condition.	76*	31	29
My skin hurts.	-1	65*	50*
My skin condition burns or stings.	18	55*	38
My skin itches.	-2	72*	29
Water bothers my skin condition (bathing, washing hands).	59*	54*	31
My skin is irritated.	7	82*	12
My skin is sensitive.	27	64*	37
My skin condition bleeds.	-3	54*	30
My skin condition affects how well I sleep.	27	65*	23
My skin condition makes it hard to do work or do hobbies.	61*	49	37
My skin condition affects my social life.	38	32	62*
I tend to stay at home because of my skin condition.	51*	39	57*
My skin condition affects how close I can be with those I love.	19	20	86*
I tend to do things by myself because of my skin condition.	20	49	59*
My skin condition makes showing affection difficult.	24	-16	84*
My skin condition affects my interactions with others.	46	38	58*
My skin condition is a problem with the people I love.	33	-10	77*
My skin condition affects my desire to be with people.	58*	28	57*
My skin condition interferes with my sex life.	21	-17	74*
My skin condition makes me tired.	28	20	58*
Cronbach α coefficient	0.951	0.887	0.935

Abbreviation: CTCL, cutaneous T-cell lymphoma.
*Factor loading score of 50 or higher.

specific HRQOL questionnaire covering physical, social, psychological, and general well-being. Comparison of HRQOL scores with concurrent skin stages was used to test the validity of the questionnaire. However, there were no data on reliability, test-retest reliability, internal consistency, or responsiveness to change.

Table 7. Comparison of HRQOL Instruments Used in Acne Vulgaris, Psoriasis, and CTCL

Source	HRQOL Instrument	Medical Condition Evaluated
Lasek and Chren ²³	Skindex-29	Acne vulgaris
Weiss et al ²⁴	Patients general perception of their psoriasis Satisfaction with life scale Euro-QOL 5D SF-36	Psoriasis
Krueger et al ²⁵	A 4-page self-administered questionnaire on demographic characteristics, incidence and severity of psoriasis, psychosocial impact of the disease, type of psoriasis, symptoms, use of available therapies, and awareness of National Psoriasis Foundation	Psoriasis
Wahl et al ²⁶	SF-36	Psoriasis
Olsen et al ¹⁷	FACT-G (3rd version)	CTCL
Duvic et al ^{30,31}	Spitzer questionnaire Nonvalidated CTCL specific questionnaire	CTCL
Bisaccia et al ³²	A 20-item CTCL-specific HRQOL questionnaire	CTCL

Abbreviations: CTCL, cutaneous T-cell lymphoma; FACT-G, Functional Assessment of Cancer Therapy-General; HRQOL, health-related quality of life; SF-36, Medical Outcomes Study Short Form Health Survey.

The present study is the first to our knowledge to report on discrete aspects of the HRQOL of patients with CTCL as measured by both general-oncologic and skin-specific HRQOL questionnaires. The importance of combining both instruments in assessing the extent of HRQOL impairment is highlighted by the recent literature in psoriasis research. The combination of a generic and a dermatology-specific questionnaire has been recommended for psoriasis research.³³ Furthermore, on the basis of psychometric data, Skindex-29 was found to be the most valuable dermatology-specific questionnaire for psoriasis research.³³ While the present study did not include a generic questionnaire such as the SF-36 (Medical Outcomes Study Short-Form Health Survey),³⁴⁻³⁹ future studies should also evaluate CTCL HRQOL with the SF-36 to better assess the extent of impairment compared with the general population.

In conclusion, we have demonstrated that HRQOL can be assessed in patients with CTCL using both FACT-G and Skindex-29. Our study findings indicate that patients with advanced-stage disease report a greater impact of CTCL on their HRQOL than do those with earlier stages. Future studies should, in addition to including the SF-36, evaluate responsiveness to change with FACT-G and Skindex-29. Since CTCL remains a relatively incurable disease, we believe that in studies of investigational agents, researchers should also assess patients' HRQOL. Focusing our efforts on improving not only the manifestations of CTCL but also patients' HRQOL should translate into improvements that are meaningful to them.⁴

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