Published in final edited form as:
Laryngoscope. 2007 March ; 117(3): 399–405.

The Skin Cancer Index: Clinical Responsiveness and Predictors of Quality of Life

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Abstract

Objective—To establish the clinical responsiveness of the Skin Cancer Index (SCI), a new disease-specific quality of life (QOL) instrument, and to assess demographic and clinical factors which impact QOL in patients with nonmelanoma skin cancer (NMSC).

Study Design—Prospective study of 183 patients with NMSC of the face and neck referred to a tertiary care Mohs surgery clinic.

Methods—The SCI is a 15 item, validated, disease-specific QOL instrument with 3 distinct subscales, Emotion, Social, and Appearance. Higher scores reflect better QOL. The SCI and the Dermatology Life Quality Index (DLQI), a general dermatology instrument, was administered at initial consultation and 4 months after surgical treatment. Multivariate analysis was conducted to assess demographic and clinical factors predictive of QOL for both instruments.

Results—The SCI total score and all three subscale scores increased with treatment, demonstrating strong evidence of responsiveness over time ($P < .001$) in contrast with the DLQI ($P = .46$). Predictors of poorer QOL for the SCI included female sex and cancers located on the lip. Patients who demonstrated greatest improvement in QOL with treatment included those who were younger (< 50 yr) and had lower reported household income. Also, first time NMSC patients and those patients who underwent less extensive reconstructions demonstrated greater improvements in QOL.

Conclusion—The SCI is a sensitive and responsive QOL instrument for patients with NMSC. Distinct demographic and clinical variables that impact QOL have been demonstrated using this multidimensional, disease-specific instrument.

Keywords

Skin cancer; quality of life; basal cell cancer; squamous cell cancer

INTRODUCTION

Nonmelanoma skin cancers (NMSCs) remain a major public health problem, with over 1.3 million new cases diagnosed annually in the United States, with the incidence of NMSC expected to double in the next 30 years.[1] NMSC is a unique cancer in that the seriousness of

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This research was in part funded by an educational grant from the American Society for Dermatologic Surgery and the National Institutes of Health/National Cancer Institute R03 CA108271.

the cancer is relatively less as it relates to a traditional endpoint measures such as mortality rate; yet, the disease process often involves an area of the body that is visually conspicuous to self and others. Disease progression and treatment of NMSCs may lead to potential morbidity in terms of physical deficits or issues related to disfigurement.

Our previous quality of life (QOL) studies in this patient population indicated that there were domains of QOL that were not captured by existing instruments.[2–4] In particular, the emotional domains (anxiety, worry) as well as issues related to potential embarrassment and body image appeared to warrant further investigation. The results of our previous studies led us to the conclusion that existing QOL measures were relatively insensitive for patients with NMSC and that a disease-specific QOL measure for NMSC was needed.

The Skin Cancer Index (SCI) was developed to capture the relevant issues for this patient population and to start the process of understanding how this disease and its treatment impact patients' lives. We have previously reported the initial development and validation processes for the SCI.[5–7] The objective of this study was to demonstrate its responsiveness to clinical change and to identify variables that may predict QOL scores and its patterns of change.

METHODS

The SCI was developed on the basis of a literature review, semistructured patient interviews, and input from an expert panel of physicians and nurses specializing in otolaryngology, dermatology, oculoplastic surgery, and plastic surgery. The SCI is a 15 item QOL instrument with 3 distinct subscales, Emotion, Social, and Appearance. Standardized scores range from 0 to 100, with higher scores reflecting higher QOL. Construct and face validity, reliability and other validation procedures have been previously reported.[5–7]

The sample was composed of 211 patients with a biopsy proven NMSC of the face or neck referred to a dermatologic Mohs surgery clinic in a large Midwestern teaching hospital. Enrollment and follow-up spanned the period between February 1, 2005 to March 2006. This cohort was part of the initial cross-sectional, validation study reported previously (baseline, presurgery data).[7] Inclusion criteria consisted of sufficient physical and mental capacity, adult age, and fluency in written and spoken English. Participants with major psychiatric illnesses or cognitive impairment were excluded because these factors could confound assessment. All participants were evaluated at the initial clinical visit before discussions of therapeutic interventions. A trained research nurse explained the research study to the participants and obtained an informed consent approved by the institutional review board.

Data collected included demographic and clinical information. Demographic variables included age, sex, marital status, education level, and socioeconomic status (employment, income). Clinical variables included type of cancer, location, size, primary versus recurrence, and number of concurrent comorbid conditions (e.g., diabetes, hypertension, coronary artery disease, etc.).

A battery of instruments was administered at the initial consultation. Convergent and divergent validity assessment of the SCI with other existing scales has been previously reported.[7] Of these measures, only the Dermatology Life Quality Index (DLQI) was administered alongside the SCI at the 4 month post-surgery mark to compare responsiveness over time. The DLQI is a generic, dermatologic QOL instrument that has been previously used in patients with NMSC.[8] High scores in this instrument indicate worse QOL (range 0–30).

All patients were seen within 1 week of surgery. Additional follow-up appointments were dictated by the clinical situation. All patients were scheduled for a 4 month follow-up appointment. The 4 month endpoint was chosen to correspond to the time when the majority

of postoperative healing process has finished (i.e., able to evaluate the "final" postoperative result). If the patient was not able to make the scheduled appointment, the questionnaire was sent with self-addressed stamped enveloped to the home address. Three attempts were made to contact the participant to fill out the follow-up questionnaire.

Statistical Analysis

Summary statistics were computed for each SCI question, the three SCI raw subscale totals, and the raw overall SCI total. The subscales were transformed so that each subscale, and the total, was between 0 and 100. Details of scoring and transformation of SCI scores have been previously reported.[7] Standardized scores were used in all subsequent analyses. Confidence intervals for the mean of each SCI subscale, the SCI total, and the DLQI total scores were calculated for the presurgery and postsurgery time points and for the change from pre- to postsurgery. Equality of means between pre- and postsurgery was analyzed using the paired *t* test.

Multivariate analysis was performed using mixed models for repeated measures data, with several between subject factors and one within-subject factor (time, two levels; presurgery and postsurgery). Between subject factors included demographic factors (age, employment, sex, marital status, educational attainment, income) and clinical factors (location of lesion, number of different locations, histology, previous treatment, existence of comorbid conditions, and reconstruction technique). Assumptions of mixed models including normality of sampling distributions and homogeneity of variance-covariance matrices were checked. Least squares estimates of means for main effect variables (no interaction with time) and for variables interacting with time were performed. *P* values less than or equal to .05 were considered significant.

RESULTS

All of the 211 eligible patients enrolled in the study reported for their routine 1 week follow-up appointment. However, follow-up data at 4 months was available for 183 patients (87% completion rate), mainly because of patient's active or passive unwillingness to participate in the study. Nine additional patients were dropped from the multivariate analysis because of missing income data. Descriptive statistics for participants' demographic and clinical characteristics are shown in Table I.

The responsiveness of the SCI was tested using a paired *t* test. Means and 95% confidence intervals are presented in Table II for each SCI score outcome: presurgery, postsurgery, and the difference between the scores. The results indicate that the total SCI scores and all three of the subscales were significantly higher postsurgery when compared with the baseline scores. In contrast, the DLQI mean did not change significantly (Table II).

In the multivariate analysis, mixed models for repeated measures were used to assess effects of demographic or clinical variables on SCI scores and the DLQI score (Table III). Significant main effects for the SCI total included sex and location of lesion. Those patients who had lip involvement or were female demonstrated poorer QOL. In evaluating interactions with time for the SCI outcomes, patients who were younger (<50 yr old), reported lower reported household income, had no previous NMSCs, and had less complex reconstructions demonstrated significantly greater QOL improvement after treatment compared with their peers (Table IIIA).

The multivariate analyses of the SCI subscales and the demographic and clinical predictors showed similar main effects and interactions with time. Age, income, involvement of cancer

on the lip, sex, and previous treatment were all significant variables in the mixed models (Table III, B to D).

For the DLQI, the significant main effects that predicted poorer QOL included cancers involving the cheek, "other" locations, and female sex. Similarly, as in the case with the SCI, younger age (<50 yr old) and less complex reconstructions were predictive variables for greater QOL improvements after surgery (Table IIIE).

DISCUSSION

We have demonstrated that the SCI is a highly sensitive and clinically responsive measure of QOL changes for NMSC patients. We had anticipated that the SCI would show improvement in scores between presurgery and postsurgery status because, in contrast with some other disease processes, our previous studies using generic and skin QOL instruments for this population had demonstrated an overall improvement in QOL after treatment. This improvement in scores occurred for all of the subscales of the SCI, which suggests that all of the subscales are able to capture the response to clinical intervention. In our previous validation study, principal components factor analysis had confirmed the multidimensionality of the SCI.[7] This study further demonstrates the distinct nature of each subscale along with its individual responsiveness to clinical change.

In reviewing available QOL instruments for comparison with the SCI, the DLQI appeared to be the most appropriate for this population. The DLQI is a validated 10-item general dermatologic questionnaire developed in the United Kingdom that has been used previously to study NMSC patients.[8] Unlike the SCI, there are no distinct subscales in the DLQI, although the individual items do address some similar concerns as in the SCI. However, the DLQI items appear to be more tailored for chronic, benign skin conditions such as psoriasis or eczema because they emphasize physical complaints of itchiness and irritation and do not capture issues related to scarring, disfigurement, and worry about recurrence or new lesions. As found in past studies, our results indicate that the DLQI is not responsive to clinical intervention for this set of patients.[3,8] Nevertheless, as in the SCI, the DLQI was sensitive enough to differentiate some variables that were predictive of differences in QOL.

Studies have shown that the diagnosis and treatment of other cancer types with disfigurement issues have a variety of negative psychologic effects.[9–11] Also, emotional difficulties with QOL alterations have been demonstrated in nonmalignant dermatologic disorders such as acne and eczema.[12,13] In our study, female sex was predictive of poorer QOL as a main effect for the SCI total score, SCI appearance subscale, and the DLQI. Female sex also predicted greater improvement in QOL over time for the SCI appearance subscale. The sex differences are consistent with some studies that have made the argument that women may experience greater difficulty adapting to cervicofacial cancers because they may potentially value facial attractiveness more than men.[11,14] However, there are some conflicting studies that point to the moderating effect of greater use of social support by women that lessen the psychosocial impact of potentially disfiguring disease or treatment.[11,15] We did not screen for psychologic disorders such as depression or anxiety in our study, which may confound the finding of sex differences. Some past studies have demonstrated higher rates of these psychologic conditions in females with head and neck cancer.[16,17]

Younger patients (<50 yr old) demonstrated poorer QOL as a main effect for the SCI appearance subscale. Also, younger patients had poorer QOL preoperatively but demonstrated greater improvement in QOL with treatment than their older counterparts. This finding was demonstrated in the SCI total, SCI emotion subscale, SCI social subscale, and the DLQI. In a previous study using a generic cancer QOL instrument, we similarly demonstrated that younger

patients with NMSC, especially those who were employed, showed greater improvement in their emotional QOL scores compared with their unemployed counterparts.[2] In the present study, almost the entire younger patient cohort was employed. This group of patients may be particularly sensitive to the conspicuous nature of the disease as it relates to potential disfigurement and scarring in the workplace.

Clinical factors such as NMSCs located on the lip and those requiring more extensive reconstructions were found to correlate with lower SCI scores and therefore poorer QOL. These findings do make intuitive clinical sense. Cancers located on the lip may be considered “more serious” by the patients because of the potential functional and esthetic implications of the disease or its treatment. Similarly, a less extensive reconstruction such as primary closure may be perceived by the patient as “less serious” and therefore account for the greater improvement in QOL. It is also possible that the less extensive reconstruction may reflect less disease burden or less conspicuous scars, which may translate to greater improvements in QOL scores.

Although the statistical difference is modest, patients who have had previous NMSCs did not demonstrate as large of an improvement in QOL with treatment when compared with first-time NMSC patients. Patients with recurrent or new NMSCs appear to recognize the potential long-term implications of the disease, with the high likelihood of a new NMSC within the next several years. This understanding of the chronic or recurrent nature of the disease may be tempering the QOL improvement change with treatment.

Lower household income was found to be predictive for greater improvement in QOL with treatment (SCI total) but lower baseline scores (SCI total, SCI social). We did not investigate which factors may be contributing to worse QOL at diagnosis for this group of patients. It is possible that the disease or its treatment may have a greater socioeconomic impact on this group of patients. Interestingly, the difference in QOL scores becomes nonsignificant between the groups postoperatively.

We have demonstrated that the SCI is a sensitive and responsive QOL instrument for NMSC patients. The creation of a valid measurement tool will potentially serve as an outcome measure in future intervention studies that aim to improve QOL of this ever growing population. Currently, surgical removal, as in our study, remains the mainstay for the vast majority of patients with NMSC. However, the recent advent of topical 5-fluorouracil and immune response modifiers along with an increasing interest in laser or photodynamic therapy for treatment of NMSC highlight the burgeoning field of nonsurgical options.[18] In certain situations, nonsurgical treatments may offer some advantages in terms of reduction of scarring and better cosmetic results. However, the unproven cure rate, length of treatment, and associated discomfort of these nonsurgical options may potentially negatively impact patient QOL.

Finally, our study cohort was relatively homogeneous in its ethnic diversity, clinical presentation, and geographic location. For our patient population, we have demonstrated some distinct demographic and clinical variables that impact QOL using this multidimensional, disease-specific instrument. Such information may help clinicians target at-risk groups in terms of perioperative counseling or psychosocial intervention. We encourage the use of the SCI to investigate differences in perceptions of illness among other ethnic groups, between regions of the country, and among certain NMSC clinical subgroups (e.g., immunocompromised patients, varying anatomic locations, size/severity of disease).

CONCLUSION

The SCI is a sensitive and responsive QOL instrument for patients with NMSC. Distinct demographic and clinical variables that impact QOL have been demonstrated using this

multidimensional, disease-specific instrument. This instrument will potentially serve as an important outcome measure in future studies that aim to improve the QOL for this patient population.

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TABLE I

Descriptive Data for Sociodemographic and Medical Characteristics.

Variable Level	n	Percent
Overall	183	
Sex		
Female	93	51
Male	90	49
Race		
White	182	99
American Indian/Aleut/Eskimo	1	1
Age, median (range)	63 (21–85)	
<50	30	16
50–64	65	36
≥65	88	48
Education		
High school or less	46	25
Vocational school or some college	48	26
College degree	57	31
Professional or graduate degree	32	17
Marital status		
Married/live-in partner	140	77
Other	43	23
Income		
<10K	4	2
10–20K	11	6
20–30K	18	10
30–50K	28	15
50–70K	32	17
>70K	81	44
Missing	9	5
Job status		
Full-time	67	37
Part-time	18	10
Self-employed	14	8
Retired	63	34
Homemaker	16	9
Other	5	3
Location of lesion		
Nose	56	31
Lips	16	9
Eyelid	23	13
Ears	18	10
Cheek	25	14
Forehead	18	10
Temple	11	6
Neck	1	1
Scalp	7	4
Other	29	16
Number of different locations		
1	164	90
2	17	9
3	2	1
Histology		
Basal	164	90
Squamous	16	9
Other	3	2
Previous treatment		
None	115	63
Same Site/Recurrent	23	13
Other site	45	25
Comorbidity		
Present	154	84
Absent	29	16
Reconstruction type		
None	21	11
FTSG	13	7
Local flap	60	33
Regional flap	5	3
Primary closure	95	52

FTSG = full-thickness skin graft.

TABLE II

Quality of Life Scales Across Time for Nonmelanoma Patients.

Instrument	Subscale	Presurgery		Postsurgery		Difference		*P* Value
		Mean	95% Confidence Interval	Mean	95% Confidence Interval	Mean	95% Confidence Interval	
SCI	Emotion	60.1	(56.3, 63.8)	69.7	(66.8, 72.6)	9.6	(6.7, 12.5)	<.001
	Social	81.7	(79.0, 84.5)	88.0	(86.0, 90.0)	6.3	(4.0, 8.6)	<.001
	Appear	63.2	(58.9, 67.4)	74.3	(70.8, 77.8)	11.1	(7.7, 14.5)	<.001
	Total	68.3	(65.2, 71.4)	77.3	(75.0, 79.7)	9.0	(6.7, 11.3)	<.001
DLQI	Total	2.1	(1.8, 2.4)	1.9	(1.6, 2.3)	−0.1	(−0.5)	.460

Means and 95% confidence intervals are presented for Skin Cancer Index (SCI) and Dermatology Life Quality Index (DLQI).

TABLE III

Demographic or Clinical Predictors of Main Effects or Interactions With Time for Quality of Life Scales.

Main Effects Variable Level	Mean		*P* Value
A. Multivariate Analysis of SCI Total Score			
Lesion on lip			.014
Absent	67.9 (64.5, 71.3)		
Present	57.6 (49.3, 65.9)		
Sex			.005
Female	59.3 (54.2, 64.5)		
Male	66.2 (60.5, 71.9)		
Interaction Effects With Time Variable Level	**Presurgery Mean**	**Postsurgery Mean**	***P* value**
Age			<.001*
<50	46.8 (39.2, 54.4)	65.2 (57.6, 72.8)	<.001†
≥50	66.4 (61.9, 70.9)	72.6 (68.2, 77.1)	<.001†
P value‡	<.001	.039	
Income			.050*
<50K	51.8 (45.3, 58.2)	66.5 (60.0, 72.9)	<.001†
≥50K	61.4 (56.3, 66.6)	71.4 (66.2, 76.5)	<.001†
P value‡	<.001	.081	
Reconstruction			.007*
None/primary closure only	55.2 (49.5, 60.8)	70.6 (65.0, 76.2)	<.001†
Skin graft/flap	58.1 (52.1,64.0)	67.2 (61.3, 73.1)	<.001†
P value‡	.285	.207	
Previous treatment			.004*
None	55.4 (50.1, 60.7)	71.1 (65.8, 76.4)	<.001†
New site/recurrent	57.8 (51.6, 64.1)	66.8 (60.5, 73.0)	<.001†
P value‡	.371	.115	
B. Multivariate Analysis of SCI Emotion Subscale			
Main Effects Variable Level	**Mean**		***P* value**
Income			.002
<50K	54.4 (48.4, 60.4)		
≥50K	64.4 (60.1, 68.7)		
Interaction Effects With Time Variable Level	**Presurgery Mean**	**Postsurgery Mean**	***P* value**
Age			.001*
<50	43.7 (35.4, 51.9)	64.2 (55.9, 72.4)	<.001†
≥50	61.2 (57.5, 64.9)	68.6 (64.8, 72.3)	<.001†
P value‡	<.001	.330	
C. Multivariate Analysis of SCI Social Subscale			
Main Effects Variable Level	**Mean**		***P* value**
Income			<.001
<50K	76.0 (71.8, 80.2)		
≥50K	84.2 (81.1, 87.3)		
Interaction Effects With Time Variable Level	**Presurgery Mean**	**Postsurgery Mean**	***P* value**
Age			.005*
<50	68.4 (62.5, 74.4)	81.2 (75.3, 87.2)	<.001†
≥50	83.3 (80.6, 86.1)	87.3 (84.6, 90.0)	.003†
P value‡	<.001	.063	
Reconstruction			.005*
None/primary closure only	74.2 (70.2, 78.2)	86.0 (82.0, 90.0)	<.001†
Skin graft/flap	77.5 (73.2, 81.8)	82.5 (78.2, 86.8)	.016†
P value‡	.178	.157	
Previous treatment			.028*
None	73.5 (69.8, 77.1)	84.6 (80.9, 88.2)	<.001†
New site/recurrent	78.3 (73.7, 82.9)	84.0 (79.4, 88.6)	.012†
P value‡	.055	.815	
D. Multivariate Analysis of SCI Appearance Subscale			
Main Effects Variable Level	**Mean**		***P* value**
Lesion on lip			.033
Absent	64.0 (59.7, 68.3)		
Present	52.3 (41.5, 63.1)		
Age/Employment status			<.001
<50	49.5 (40.5, 58.5)		

≥50	66.8 (61.2, 72.3)		
Interaction Effects With Time Variable Level	Presurgery Mean	Postsurgery Mean	*P value*
Previous treatment			.002*
None	50.9 (44.2, 57.7)	66.0 (59.3, 72.7)	<.001†
New site/recurrent	55.7 (47.7, 63.6)	60.0 (52.0, 67.9)	.120†
P value‡	.193	.097	
Sex			.017*
Female	42.2 (35.2, 49.2)	55.9 (48.9, 62.9)	<.001†
Male	64.4 (56.8, 72.0)	70.1 (62.4, 77.7)	.020†
P value‡	<.001	<.001	

E. Multivariate Analysis of DLQI Total Score

Main Effects Variable Level	Mean		*P* value
Lesion on cheek			.019
Absent	2.5 (2.1, 3.0)		
Present	1.6 (0.7, 2.4)		
Lesion on other location			.018
Absent	1.6 (1.1, 2.1)		
Present	2.5 (1.7, 3.3)		
Sex			.006
Female	2.4 (1.8, 3.1)		
Male	1.7 (1.1, 2.3)		
Interaction Effects With Time Variable Level	Presurgery Mean	Postsurgery Mean	*P* value
Age			<.001*
<50	3.0 (2.1, 3.9)	1.6 (0.7, 2.5)	.001†
≥50	1.8 (1.2, 2.3)	1.9 (1.4, 2.5)	.359†
P value‡	.005	.418	
Reconstruction			.012*
None/primary closure	2.7 (2.1, 3.4)	1.7 (1.0, 2.3)	<.001†
Skin graft/flap	2.0 (1.3, 2.7)	1.8 (1.1, 2.6)	.560†
P value‡	.033	.615	

Least squares estimates of means for main effect variables (no interaction with time) are provided with 95% confidence intervals and a *P* value testing the main effect. For variables having a significant interaction with time, least squares estimates of means and 95% confidence intervals are provided both pre- and postsurgery for each level of the variable.

** P* value testing for interaction.

† P value testing for changes over time for each level of variable.

‡ P value testing for differences between levels of variable both pre- and postsurgery.

SCI = Skin Cancer Index; DLQI = Dermatology Life Quality Index.