Validation of a Quality-of-Life Instrument for Patients With Nonmelanoma Skin Cancer

John S. Rhee, MD, MPH, **B. Alex Matthews, PhD**, **Marcy Neuburg, MD**, **Brent R. Logan, PhD**, **Mary Burzynski, RN**, and **Ann B. Nattinger, MD, MPH**
Department of Otolaryngology and Communication Sciences (Dr Rhee and Ms Burzynski), Health Policy Institute, Center for Patient Care and Outcomes Research (Drs Matthews and Nattinger), Division of Biostatistics (Dr Logan), and Department of Dermatology (Dr Neuburg), Medical College of Wisconsin, Milwaukee

Abstract

Objective—To validate a disease-specific quality-of-life instrument—the Skin Cancer Index— intended to measure quality-of-life issues relevant to patients with non-melanoma skin cancer.

Methods—Internal reliability, convergent and divergent validity with existing scales, and factor analyses were performed in a cross-sectional study of 211 patients presenting with cervicofacial nonmelanoma skin cancer to a dermatologic surgery clinic.

Results—Factor analyses of the Skin Cancer Index confirmed a multidimensional scale with 3 distinct subscales—emotional, social, and appearance. Excellent internal validity of the 3 subscales was demonstrated. Substantial evidence was observed for convergent validity with the Dermatology Life Quality Index, Rosenberg Self-Esteem Scale, Lerman's Cancer Worry Scale, and Medical Outcomes Survey Short-Form 12 domains for vitality, emotion, social function, and mental health.

Conclusions—These findings validate a new disease-specific quality-of-life instrument for patients with cervicofacial nonmelanoma skin cancer. Studies on the responsiveness of the Skin Cancer Index to clinical intervention are currently under way.

Nonmelanoma skin cancers (NMSCs) are the most common cancers among humans and continue to be a major public health concern.[1] Nonmelanoma skin cancers usually occur in the most conspicuous locations of the body, with approximately 80% in the cervicofacial region. Disease progression and treatment of NMSCs arising in these locations may lead to adverse consequences such as physical, functional deficits and psychosocial issues related to potential disfigurement.[2]

A variety of generic and skin-related instruments have been used to measure the effect on quality of life (QOL) for patients with NMSC.[3–7] However, results of our previous studies point to the need for a disease-specific QOL instrument because existing measures were not sensitive for this population.[5,6] We previously reported the initial conceptual framework and developmental processes for the Skin Cancer Index (SCI), a new disease-specific QOL instrument for patients with NMSC.[8] We also reported the findings of the initial item-reduction phase, creation of subscales, and test-retest validation procedures.[9] The objective of this study was to validate and refine the SCI further.

Correspondence: John S. Rhee, MD, MPH, Department of Otolaryngology and Communication Sciences, Medical College of Wisconsin, 9200 W Wisconsin Ave, Milwaukee, WI 53226 (jrhee@mcw.edu).

METHODS

Details of the initial developmental phases of the SCI were reported previously.[8,9] In brief, stage I entailed developing a comprehensive list of items regarding QOL issues on the basis of information obtained from patients, experts in the field, and existing literature. Patient information was obtained from semistructured interviews. Stage II entailed obtaining feedback from another sample of patients with NMSC who previously underwent treatment; the purpose was to establish item relevance, comprehensibility, and completion time. After statistical analysis, the number of items was reduced, and only the most relevant were retained. Stage III involved 2 sequential test-retest procedures to address reliability across time and order effects and to refine the items and subscales further.

When the initial phases were complete, the field-tested version of the SCI contained 20 items with 4 subscales, consisting of 7 emotional items, 5 social items, 4 appearance items, and 4 work/financial concerns. A standard 5-point Likert response format was used to assess to what extent each item described the patient's feelings.

STUDY POPULATION

The cross-sectional sample was composed of 228 patients who were referred to a dermatologic Mohs surgery clinic in a large mid-western teaching hospital because of a cervicofacial NMSC from February 1, 2005, through September 30, 2005. 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 underwent evaluation at the initial clinical visit before discussions of therapeutic interventions. A trained research nurse (M.B.) explained the research study to the participants and obtained informed consent. The study was approved by the institutional review board.

VALIDATION PROCEDURES

Summary statistics including means, standard deviations, ranges, and quartile scores were computed for each of the 20 items. Because of the different number of items per subscale, the raw scores of the items and subscales were then standardized, with a range from 0 (lowest QOL, greatest negative effect) to 100 (highest QOL, least negative effect). Standardized subscale scores were obtained by summing the individual standardized scores and then dividing by the number of items on the subscale. Total SCI score was obtained by summing the subscale scores and dividing by the number of subscales.

Internal validity was tested by computing a Cronbach α for each domain of the SCI. An α coefficient greater than .70 indicated a reliable, internally consistent scale. In the case of low α values, items with low item-total correlation coefficients were removed until a satisfactory subscale score was obtained.

Principal components factor analysis was performed to identify latent factors in the model and to determine whether the items matched the a priori subscales. The number of factors to be retained was determined by identifying the number of factors with eigenvalues greater than 1. Varimax rotation was used to identify these latent factors and their relationships to the items and subscales more readily.

Convergent and divergent validity were assessed by computing a Spearman correlation coefficient between the standardized SCI items and each of the following existing measures: the Medical Outcomes Survey Short-Form 12, version 2 (SF-12); Lerman's Cancer Worry Scale; Dermatology Life Quality Index (DLQI); Rosenberg Self-Esteem Scale; and Marlowe-Crowne Social Desirability Scale. The SF-12 is a generic, health-related QOL tool containing

12 items and measuring 8 dimensions of health status. Lerman's Cancer Worry Scale is a 6-item scale that measures psychological concerns associated with cancer. The DLQI is a 10-item generic scale for dermatologic problems. The Rosenberg Self-Esteem Scale is a 10-item scale used extensively as a unidimensional measure of self-esteem. Finally, the Marlowe-Crowne Social Desirability Scale is a 13-item questionnaire that measures an individual's tendency to respond in a culturally appropriate and acceptable manner. We predicted that higher SCI scores, indicating higher QOL, would correlate positively with higher Rosenberg Self-Esteem Scale scores and SF-12 scores in the domains measuring social, mental, and emotional well-being. Similarly, we predicted higher SCI scores would correlate inversely with DLQI and Lerman's Cancer Worry Scale scores (lower DLQI and Lerman's Cancer Worry Scale scores indicate higher QOL). We expected low or no association between the SCI and Marlowe-Crowne Social Desirability Scale scores.

RESULTS

Of the 228 patients enrolled in the study, complete data were available for 211 patients. The median age was 63 years (range, 21–85 years), almost all were white, and there were approximately equal numbers of men (48%) and women (52%). Basal cell carcinomas were found in 88% of the sample, squamous cell carcinomas were detected in 10%, and other types of lesions were found in 2%. The most common location of the cancer was the nose (31%), followed by cheek (14%), eyelid (13%), auricle (11%), forehead (11%), lips (10%), temple (5%), scalp (4%), and neck (1%).

Preliminary factor analysis and assessment of internal validity were performed on the initial 20-item SCI. After review, 1 item in the social subscale was eliminated to improve internal validity. Two items in the work/financial subscale showed low reliabilities and were removed. The remaining 2 items of the work/financial subscale had acceptable internal validity, but the items appeared to focus solely on financial issues that did not seem specific to the disease process. Therefore, we decided to eliminate the work/financial subscale altogether and then to rerun the validation procedures on the remaining items and subscales. The final SCI consisted of 15 items with 3 subscales: emotional, social, and appearance (Figure).

Table 1 lists the item-level descriptive statistics for the raw and standardized scores grouped according to domain for the 15-item SCI. The emotional subscale demonstrated the lowest standardized scores and greatest negative effect when compared with the other 2 subscales. Overall, the summary statistics indicated skewness for each of the subscales and for the total distributions, with more patients closer to the upper end of the range, indicating higher QOL.

The Cronbach α coefficients were computed for the 3 subscales. All subscales demonstrated excellent internal validity: emotional (α =.91), social (α =.82), and appearance (α =.92). Table 2 outlines the principal components factor analysis findings for the 15-item scale. Three factors with eigenvalues greater than 1 were found. These 3 factors appeared to load appropriately on the a priori subscales.

Table 3 presents the bivariate correlations between the standardized total and subscale SCI scores and other existing scales. These findings indicate that higher scores on the SCI were associated negatively with Lerman's Cancer Worry Scale and DLQI scores (less impairment of QOL) and associated positively with Rosenberg Self-Esteem Scale and several SF-12 domains (vitality, social functioning, role emotional, mental health). The SF-12 domains measuring emotional and mental health well-being demonstrated the strongest associations with the SCI. The Marlowe-Crowne Social Desirability Scale scores demonstrated no correlation with the total SCI scores or any SCI subscale scores. In total, the associations between the SCI scores and existing scales were consistent with our a priori expectations.

COMMENT

Our results indicate that the SCI is a reliable and valid QOL instrument that is simple to administer, score, and analyze. The development of specific subscales was based loosely on past QOL instrument designs but was driven largely by patient concerns and comments during the semi-structured interviews, preliminary administration, and clinical experiences. Principal components factor analysis confirmed the multidimensionality of this new scale, and the factors identified reflect the complexity and concerns of this disease process.

The appearance subscale is unique to this instrument and, to our knowledge, has not been reported in other health-related QOL instruments. Factor loadings (Table 2) support the separation and distinctiveness of the appearance items from the emotional items. The appearance subscale appears to capture the issues of disfigurement, scarring, and self-image perceptions, whereas the emotional subscale appears to focus more on issues related to the clinical course of the cancer. Item number 9 relates to patients' concerns that their disease may worry friends or family members. Although this item double-loaded on both the emotional and social subscales, the item was placed on the social subscale because it improved the internal validity for this subscale more than for the emotional subscale.

The work/financial subscale was originally part of the field-tested SCI. It consisted of 4 items that were loosely related to issues concerning health insurance coverage, financial concerns, and work limitations related to treatment. The diversity of the patient population in terms of work status made some of the items less applicable and difficult to answer appropriately. The 2 items focusing on financial concerns were more universal in nature. They were distinct items in the initial principal components factor analysis and were reasonably reliable as a subscale. However, after review of the 2 items, we thought that these items were too general, could pertain to any medical condition, and were not necessarily specific to this population. In addition, a 2-item subscale is arguably insufficient from a statistical perspective; therefore, we decided to eliminate this subscale.

Significant score correlations between the SCI and the other validated scales indicated good concurrent validity. As predicted a priori, patients with higher SCI scores, indicating higher QOL, reported less worry, less skin QOL impairment, greater self-esteem, and higher QOL in the SF-12 domains related to vitality, emotion, social function, and mental health. As anticipated, the SCI had no correlation with the Marlowe-Crowne Social Desirability Scale, indicating the lack of socially desirable response bias.

In our previous QOL studies in patients with NMSC, we heard from participants that most of the items contained in existing QOL scales were irrelevant to their situation.[4–6] Although results of these studies demonstrated some QOL alterations, the sensitivity of these instruments was low and, therefore, likely artificially diminished the recorded effect of the disease. Even with our new disease-specific instrument, the responses were moderately skewed to the upper range, which is the case with other health-related QOL tools.[10] In our study, this finding may reflect that the cohort had less severe manifestations of disease or patient illness perception. Lower QOL scores may be expected in cohorts with larger numbers of squamous cell carcinomas, greater comorbidities (such as immunosuppression), or potentially in other geographic or ethnic designations.

Despite skewness, we anticipate that our scale will show responsiveness to change in a clinical setting. The emotional and appearance subscales had lower standardized scores and, therefore, demonstrated greater negative effect on QOL. These 2 subscales, in comparison with the social subscale, have the greater potential for improvement in their QOL scores after clinical intervention. We currently are following this cohort of patients after treatment and will report the SCI's clinical responsiveness in the future. In addition, a subanalysis of predictors for

baseline QOL and subsequent change in QOL will be performed once the prospective data collection is complete.

The development of this valid measurement tool potentially will serve as an important outcome measure in future studies that aim to improve the QOL for this ever-growing population. We encourage the use of this new scale to compare emerging treatments for NMSC and for establishing population-based normative values in different ethnic groups and geographic locations.

CONCLUSIONS

We have validated the SCI, a new disease-specific QOL instrument for patients with cervicofacial NMSC. Studies measuring the scale's responsiveness to clinical change are currently under way. This instrument potentially will serve as an important outcome measure in future studies that aim to improve the QOL for this patient population.

Acknowledgements

References

1. Santmyire BR, Feldman SR, Fleischer AB Jr. Lifestyle high-risk behaviors and demographics may predict the level of participation in sun-protection behaviors and skin cancer primary prevention in the United States: results of the 1998 National Health Interview Survey. Cancer 2001;92:1315–1324. [PubMed: 11571748]

2. Davis RE, Spencer JM. Basal and squamous cell cancer of the facial skin. Curr Opin Otolaryngol Head Neck Surg 1997;5:86–92.

3. Blackford S, Roberts D, Salek MS, Finlay A. Basal cell carcinomas cause little handicap. Qual Life Res 1996;5:191–194. [PubMed: 8998487]

4. Rhee JS, Loberiza FR, Matthews BA, Neuburg M, Smith TL, Burzynski M. Quality of life assessment in nonmelanoma cervicofacial skin cancer. Laryngoscope 2003;113:215–220. [PubMed: 12567071]

5. Rhee JS, Matthews BA, Neuburg M, Smith TL, Burzynski M, Nattinger AB. Skin cancer and quality of life: assessment with the Dermatology Life Quality Index. Dermatol Surg 2004;30:525–529. [PubMed: 15056143]

6. Rhee JS, Matthews BA, Neuburg M, Smith TL, Burzynski M, Nattinger AB. Quality of life and sun-protective behavior in patients with skin cancer. Arch Otolaryngol Head Neck Surg 2004;130:141–146. [PubMed: 14967741]

7. Holfeld KI, Hogan DJ, Eldemire M, Lane PR. A psychosocial assessment of patients with basal cell carcinoma. J Dermatol Surg Oncol 1990;16:750–753. [PubMed: 2394878]

8. Rhee JS, Matthews BA, Neuburg M, Burzynski M, Nattinger AB. Creation of a quality of life instrument for nonmelanoma skin cancer patients. Laryngoscope 2005;115:1178–1185. [PubMed: 15995503]

9. Matthews BA, Rhee JS, Neuburg M, Burzynski M, Nattinger AB. Development of the FSCI: a health-related outcomes index for skin cancer patients. Dermatol Surg. In press

10. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. Med Care 1996;34:220–233. [PubMed: 8628042]

Skin Cancer Index (SCI)

The following questions ask about your views on skin cancer or its treatment and how it may affect you socially, at work, or at home, and other areas of concern. For each of the following, please indicate how much your skin cancer affects your life by marking an "X" in the **one** box that most closely matches how you feel at the present time.

During the past month, how much have you…

	Very Much	Quite a Bit	Moderately	A Little Bit	Not at All
1. Worried that your skin cancer will spread to another part of your body?	☐	☐	☐	☐	☐
2. Felt anxious about your skin cancer?	☐	☐	☐	☐	☐
3. Worried that family members may also develop skin cancer?	☐	☐	☐	☐	☐
4. Worried about the cause of skin cancer?	☐	☐	☐	☐	☐
5. Felt frustrated about your skin cancer?	☐	☐	☐	☐	☐
6. Worried that your tumor may become a more serious type of skin cancer?	☐	☐	☐	☐	☐
7. Worried about new skin cancers occurring in the future?	☐	☐	☐	☐	☐
8. Felt uncomfortable when meeting new people?	☐	☐	☐	☐	☐
9. Felt concerned that your skin cancer may worry friends or family?	☐	☐	☐	☐	☐
10. Worried about the length of time before you can go out in the public?	☐	☐	☐	☐	☐
11. Felt bothered by people's questions related to your skin cancer?	☐	☐	☐	☐	☐
12. Felt embarrassed by your skin cancer?	☐	☐	☐	☐	☐
13. Worried about how large the scar will be?	☐	☐	☐	☐	☐
14. Thought about how skin cancer affects your attractiveness?	☐	☐	☐	☐	☐
15. Thought about how noticeable the scar will be to others?	☐	☐	☐	☐	☐

Figure.
The Skin Cancer Index.

Table 1

Descriptive Statistics for the Skin Cancer Index Items and Subscales[*]

Question No.	Quality of Life Factor	Unstandardized (Raw Scores)[†]	Standardized (0–100)[‡]
1	Worry about metastases	3.54 (1.37)	63.4 (34.4)
2	Anxiousness	3.22 (1.28)	55.5 (31.9)
3	Worry about family members	3.74 (1.27)	68.5 (31.8)
4	Worry about cause of cancer	3.68 (1.26)	66.9 (31.4)
5	Frustration	3.48 (1.36)	62.0 (34.1)
6	Worry about cancer transformation	3.44 (1.33)	61.0 (33.2)
7	Worry about future cancers	2.80 (1.26)	45.0 (31.4)
	Total Emotional Subscale	**23.90** (7.37)	60.3 (26.3)
8	Uncomfortable meeting new people	4.56 (0.87)	89.0 (21.7)
9	Concern about family or friend worrying	3.79 (1.14)	69.8 (28.6)
10	Worried about going out in public	4.23 (1.06)	80.7 (26.6)
11	Bothered by people's questions	4.48 (0.89)	87.1 (22.1)
12	Embarrassed by cancer	4.31 (1.04)	82.8 (26.0)
	Total Social Subscale	**21.37** (3.83)	81.9 (19.2)
13	Worried about scar size	3.24 (1.35)	56.0 (33.7)
14	Worried about attractiveness	3.66 (1.22)	66.6 (30.5)
15	Worried about scar noticeability	3.69 (1.21)	67.2 (30.1)
	Total Appearance Subscale	**10.59** (3.51)	63.3 (29.3)
	Total Skin Cancer Index	**55.86** (12.83)	68.5 (21.5)

[*] Data are given as mean (SD).

[†] A 5-point response format was used to assess the extent each item described the feelings of the patient, with 1 (very much) to 5 (not at all).

[‡] Each item was standardized as follows: (raw score-1)×100/4. Subscale total scores were obtained by summing the individual item standardized scores and dividing by the number of items on the subscale. Total Skin Cancer Index score was computed by summing the subscale total scores and dividing by 3.

Table 2
Factor Loadings for the Skin Cancer Index Items According to A Priori Subscales

Subscale and Question No.	Factor 1	Factor 2	Factor 3
Emotional			
1	0.756[*]	0.190	0.065
2	0.737[*]	0.273	0.272
3	0.596[*]	0.176	0.202
4	0.684[*]	0.222	0.277
5	0.652[*]	0.253	0.380
6	0.773[*]	0.168	0.118
7	0.743[*]	0.216	0.269
Social			
8	0.224	0.575[*]	0.194
9	0.493	0.422	0.213
10	0.236	0.543[*]	0.497
11	0.269	0.611[*]	0.166
12	0.208	0.609[*]	0.494
Appearance			
13	0.313	0.233	0.787[*]
14	0.293	0.192	0.821[*]
15	0.168	0.352	0.807[*]

[*] Factor loadings of 0.5 or greater indicate that the question may be related to that factor.

Table 3

Score Correlation of Standardized Skin Cancer Index Subscales With Existing Instruments[*]

Instrument	Emotional	Social	Appearance	Total
Marlowe-Crowne Social Desirability Scale	0.056 (.42)	−0.043 (.53)	−0.006 (.93)	0.000 (>.99)
Lerman's Cancer Worry Scale	−0.541 (<.001)[†]	−0.480 (<.001)[†]	−0.379 (<.001)[†]	−0.531 (<.001)[†]
Dermatology Life Quality Index	−0.291 (<.001)[†]	−0.349 (<.001)[†]	−0.288 (<.001)[†]	−0.340 (<.001)[†]
Rosenberg Self-Esteem Scale	0.179 (.009)[†]	0.272 (<.001)[†]	0.137 (.048)[†]	0.217 (.001)[†]
SF-12				
Physical function	0.028 (.69)	−0.026 (.70)	−0.058 (.40)	−0.009 (.90)
Role physical	0.136 (.049)[†]	0.077 (.26)	−0.027 (.69)	0.077 (.27)
Bodily pain	0.033 (.63)	0.014 (.84)	0.026 (.71)	0.027 (.69)
General health	0.090 (.19)	0.092 (.18)	0.027 (.70)	0.074 (.28)
Vitality	0.130 (.06)	0.176 (.01)[†]	0.103 (.13)	0.148 (.03)[†]
Social function	0.120 (.08)	0.161 (.02)[†]	0.102 (.14)	0.136 (.048)[†]
Role emotional	0.246 (<.001)[†]	0.240 (<.001)[†]	0.157 (.02)[†]	0.241 (<.001)[†]
Mental health	0.230 (.001)[†]	0.230 (.001)[†]	0.288 (<.001)[†]	0.290 (<.001)[†]

Abbreviation: SF-12, Medical Outcomes Survey Short-Form 12, version 2.

[*] Data are presented as Spearman correlation coefficient (*P* value).

[†] Significant *P* values.