CLINICAL REPORT

Development and Validation of the Basal and Squamous Cell Carcinoma Quality of Life (BaSQoL) Questionnaire

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Health-related quality of life (HRQoL) is important in the management of basal cell carcinoma (BCC) and squamous cell carcinoma (SCC). Disease-specific questionnaires exist, but with important shortcomings. The aim of this study was to develop and validate a questionnaire suitable for use in all patients with BCC and those with SCC. In a 4-phase trajectory, a preliminary questionnaire was created and population-based testing (1,173 patients) carried out. The questionnaire was reduced using exploratory factor analysis and item response theory. Individual item performance was assessed using classical test theory. A total of 721 patients completed the questionnaire. The number of items was reduced to 16, covering 5 scales. Confirmatory factor analysis showed a good fit. Cronbach's αs (range 0.67–0.82) were reasonable to high with good internal consistency. In conclusion, the Basal and Squamous Cell Carcinoma Quality of Life questionnaire has good face, content and construct validity. It is useful in the wide range of BCC and SCC patients and captures HRQoL impact over different time-frames.

Key words: basal cell carcinoma; squamous cell carcinoma; health-related quality of life; questionnaire.

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The use of patient-reported outcome measures (PROMs) and, more specifically, health-related quality of life (HRQoL) in dermatology patients has increased dramatically over the past decades. It is now an essential outcome for clinical studies and in daily practice, especially in chronic inflammatory skin diseases (1, 2). In skin cancer, the use of PROMs and HRQoL has only been used over the past 2 decades and most of the focus has been on melanoma (3). Since the incidences of basal cell carcinoma (BCC) and squamous cell carcinoma (SCC) are increasing rapidly (4–6), the need for PROMs assessment including HRQoL is warranted to evaluate individual and global disease burden. Generic, cancer- or even melanoma-specific HRQoL instruments are neither content-specific nor sensitive enough to detect the impact of the, rarely life-threatening, BCCs and SCCs, which are most often treated by conventional excision. Specific issues for keratinocytic cancers is that patients are likely to develop multiple carcinomas and actinic keratosis (AK) (so-called actinic neoplasia syndrome) and that they can check their skin constantly (7).

Measurement of HRQoL in patients with BCC has been performed in several studies, using generic, cancer-related and dermatology-specific questionnaires, all reporting little to no impact (7–13).

A few disease-specific questionnaires have been developed, but these have several important shortcomings. The Skin Cancer Index (SCI) was developed and tested only in a tertiary care Mohs surgery clinic and therefore is only suitable for use in a selected population (14, 15). The Skin Cancer Quality of Life Impact Tool (SCQOLIT) has been developed as a tool for patients with non-metastatic skin cancer (16). A limitation of the SCQOLIT is that it addresses 5 psychological issues regarding 2 different aspects in one item. In contrast to the SCI and the SCQOLIT, the Skin Cancer Quality of Life Questionnaire (SCQoL) was developed and validated using modern test theory, namely Rasch analysis (17). This instrument was, however, derived from the previously developed Actinic Keratosis Quality of Life questionnaire (AKQoL) and pre-tested in a small sample (18 AK patients, 14 skin cancer patients) with the objective of distinguishing between patients with AK and those with skin cancer (18). From a content validity perspective, the above-mentioned questionnaires do not capture the psychological issues due to the behavioural changes often required to reduce sun exposure (19).

The objective of this study was to create and validate a HRQoL questionnaire suitable for use with patients with BCC and those with SCC, addressing relevant issues for patients and healthcare providers using different methodological approaches.

METHODS

Study design

The BCC- and SCC-specific HRQoL questionnaire was prepared and developed following the guidelines of the European Organisation for Research and Treatment of Cancer Quality of Life

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(EORTC QOL) group as far as possible (20–22). However, the questionnaire is not an EORTC QOL group product and was not developed internationally. The development was conducted in 4 phases, as follows.

Phase I. The main goal of phase I was to generate an extensive list of HRQoL issues relevant to patients with BCC and those with SCC. A focus group meeting to discuss and generate HRQoL issues was facilitated by 2 independent psychologists with no in-depth skin cancer knowledge. The group consisted of 10 BCC and/or SCC patients with different types and numbers of tumours, treatments, sex and age. The audio-recording of the focus group was analysed by the first author (RWS) in order to extract as many issues as possible without formal transcription. Extensive searches of the literature via PubMed (quality of life; health-related quality of life; basal cell carcinoma; squamous cell carcinoma; non-melanoma skin cancer) and semi-structured interviews with 5 healthcare providers (HCP) provided additional issues (23).

The issues were discussed by an expert panel including dermatologists, psychologists and epidemiologists to identify the relevant disease-specific domains and issues (**Fig. 1**).

The remaining issues were presented to HCP (dermatologists, plastic surgeons, ophthalmologist, head-neck ear nose and throat (ENT) surgeon, general practitioners) and patients for feedback and cognitive debriefing. They were also asked to rate the issues for relevance from 1 (not relevant) to 4 (very relevant) on a Likert scale (relevance rating). Issues with relevance mean score ≥1.5 were selected for priority rating. HCP and patients were asked to select 15 core issues to be included in the questionnaire (priority rating). Priority ratings of ≥30% were scored in the HCP group and ≥20% in the patient group. Issues scoring ≥3 criteria were included in the final issue list (20).

Phase II. The final issue list was rephrased into questions compatible with the EORTC QLQ-C30 in terms of format of response categories (24). The time-frame of the questions was divided into 3 parts ("since diagnosis", "time between diagnosis and treatment" and "during the past week") since the items fitted different time-frames.

Phase III. The item questionnaire was pre-tested in 16 patients.

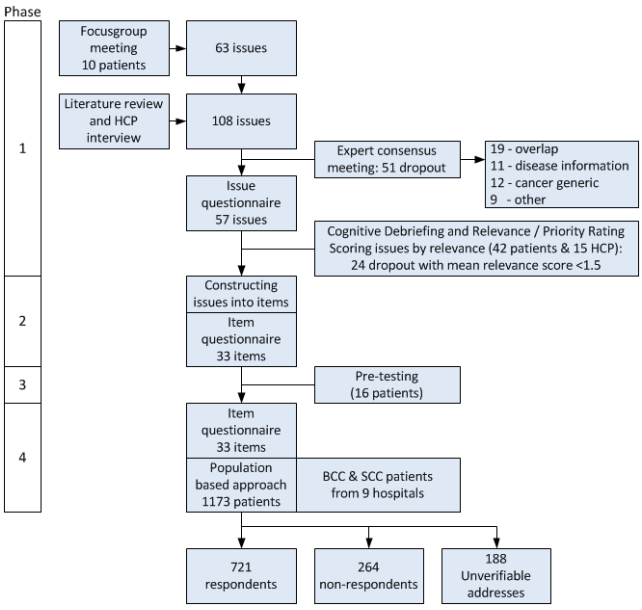

Fig. 1. Questionnaire development phases. HCP: healthcare professional; BCC: basal cell carcinoma; SCC: squamous cell carcinoma. Phase number as described by the European Organisation for Research and Treatment of Cancer quality of life (EORTC QOL) group guidelines.

Phase IV. The questionnaire was field-tested in 1,173 patients selected from the Netherlands Cancer Registry, as collected by the Comprehensive Cancer Centre Netherlands, in Eindhoven. Patients were selected if they had been diagnosed in one of the 9 participating hospitals or clinics during the past 12 months before the field-testing. The aim of the field-testing was to determine scale structure, reliability, validity and to reduce the number of items. The Skindex-17 and the QLQ-C30 were also administered.

Statistical analysis

Descriptive statistics (means and percentages) were used in phase II to calculate relevance and priority ratings of the issue list and in phase IV to describe the patient characteristics. Type of BCC was grouped as multifocal (8091 in the International Classification of Disease for Oncology; ICD-O3), infiltrating (8092), nodular (8097), or other (8090, 8093, 8094, 8095). Aforementioned analyses were performed in IBM SPSS Statistics for Windows, Version 21.0 (Armonk, New York: IBM Corporation).

After phase IV, the components were determined using principal component analyses (PCA) with varimax rotation. The number of components was determined with a Monte Carlo PCA for parallel analysis (25). Two PCAs were performed; one with complete cases and one with mean substitution, with a maximum of one missing. Items with loadings > 0.40, were selected for item response theory (IRT) (26). IRT was used to select a minimum number of the best discriminating items covering the whole range of latent traits.

For IRT analysis, we applied the 2-parameter latent trait model (2PL-ltm) (27) of the ltm package in R version 3.0.0. The 2PL-ltm program results in an ordering of the items on a given trait or component and supplies a discrimination value for each item. The 2PL-ltm programme needs binary items as input. By collapsing the 4-answer category to binary items, some loss of information is induced. This method is preferred over multi-category models, because these do not provide an ordering of the items.

The original categories were "not at all", "a little", "quite a bit" and "very much". For the majority of items the median was between the first and second category, and for this reason we dichotomized between "not at all" and "a little" or more.

The items were selected on the basis of their position on the relevant trait or component and their discriminative value. As we postulated an absolute maximum of 5 items per subscale, we divided the range between the lowest and highest position by 5, and we chose from each of these intervals the item with the highest discriminative value. We checked the unidimensionality of the remaining items with the "unidim" test of the ltm package.

After the item reduction by the 2PL-ltm model, item performance features as used in classical test theory (CTT) were tested. The definitions of the features are presented in Table SI[1] (28, 29). Descriptive statistics were used to test item difficulty (missing responses) and response distribution. Spearman's correlation coefficients were calculated for item-test and item-rest correlation, and to test item discriminant validity. Internal consistency was tested via Cronbach's α coefficients. Stepwise regression was performed in order to check the percentage of variance explained by the items in a subscale. The multitrait-multimethod correlation matrix was used to assess convergent and discriminant validity.

The resulting factors were also tested with oblique confirmatory factor analyses. We applied 2 analyses; a complete cases analysis and a maximum likelihood analysis with missing values. The fit indices were evaluated according to the recommendations of Hu & Bentler, Kline, and Brown (30–32). The correlations between the subscales were reported. The confirmatory factor analyses were performed with STATA version 14.1 (College

[1]https://www.medicaljournals.se/acta/content/abstract/10.2340/00015555-2806

Station, TX, USA). All p-values were 2-sided and considered significant if $\alpha < 0.05$.

RESULTS

Phase I–IV

The focus group meeting resulted in 63 issues, which were extended to 108 issues after literature searches and HCP interviews (Fig. 1). After an expert consensus meeting 51 issues were removed from the list due to overlapping issues, questions concerning information about the disease, cancer generic issues, or other problems that were considered outside of the domain of HRQoL.

The remaining 57 issues were rated (mean scores, range, relevance and priority rating) by 42 patients (mean age 70 years, 1–30 years since diagnosis, 27 BCC, 5 SCC and 10 diagnosis unknown to the patient) and 15 HCP (7 dermatologists, 1 plastic surgeon, 1 head neck ENT-surgeon, 1 ophthalmologist, 1 radiation oncologist and 4 general practitioners) and resulted in the removal of the 24 issues with lowest relevance and priority ratings (Fig. 1).

The remaining 33 issues were constructed into a provisional 33-item questionnaire (Table SII[1]).

Table I. Patient characteristics

	Respondents *n* = 721	Non-respondents *n* = 264	Unverifiable addresses *n* = 188	*p*-value
Sex, %				0.0063
Male	51	37	49	
Female	49	63	51	
Age				
Mean ± SD	67.3 ± 1.8	71.4 ± 13.5	61.3 ± 15.1	< 0.0001
Median, IQR	68, 15	74.5, 16	61.5, 22.5	
< 39 years	1	2	9	< 0.0001
40–49 years	8	7	16	
50–59 years	14	9	21	
60–69 years	31	18	22	
70–79 years	32	33	18	
> 80 years	14	31	13	
SCC (%)	15	16	9	0.0560
Socioeconomic status				
Low	17	22	13	< 0.0001
Intermediate	28	29	20	
High	29	31	18	
Institute	3	4	4	
Unknown	23	13	46	
Location of tumour				
Face	78	78	85	0.1000
Other	22	22	15	
Other skin tumours[a]				
Multiple BCC	16	19	11	0.1000
Multiple SCC	9	7	6	[b]
MM	0	0	1	[b]
Other	0	0	0	[b]
BCC, *n*	613	222	171	
Type BCC, %				
Multifocal	11	8	9	0.070
Infiltrating	18	22	15	
Nodular	64	65	65	
Other	7	4	12	

[a]Patients can have combinations. [b]No statistical test performed due to low numbers. SD: standard deviation; IQR: interquartile range; BCC: basal cell carcinoma; SCC: squamous cell carcinoma; MM: malignant melanoma.

This provisional questionnaire was reviewed by 16 patients for readability, clarity of the items and overlapping of the items and none of the items were excluded or rephrased.

Field testing was performed by selecting 1,173 patients with BCC or SCC from 9 hospitals. The response rate was 61% and 721 patients completed the questionnaire (**Table I**). Of all respondents 85% had BCC and 15% had SCC.

The data contained 582 complete cases, 63 cases with one missing value and 76 cases with more than one missing value.

Principal component analyses

The 2 PCAs (complete cases and with one missing included) both resulted in 6 components, with the same items loading. Items 23 and 24 formed a separate component, and at face value these items are nearly identical. Leaving out one of them resulted in 5 components. Item 24 had a higher factor loading than item 23; for this reason item 23 was removed from the analyses. Only item 5

Table II. Subscales and item characteristics

	Missing values	Principal component loading	2PL-ltm solution		Selected BaSQoL items	Unidim *p*-value
			Position	Discrimination		
Worries					α=0.82	0.0297
19	2	0.764	0.013	2.609	10	•
17	1	0.724	−0.404	3.056	9	•
25	0	0.696	0.249	2.079	12	•
26	0	0.665	−0.164	2.206		
21	2	0.646	0.827	2.472	11	•
28	0	0.630	−0.458	2.357		
18	1	0.626	−0.219	2.247		
24	1	0.482	−0.115	0.619		
10	2	0.401	0.035	1.112		
Appearance					α=0.71	0.6733
33	0	0.787	1.239	5.025	15	•
31	1	0.779	1.151	4.414		
29	0	0.770	1.144	3.987		
22	2	0.725	1.008	3.389	13	•
30	3	0.661	1.253	3.06		
15	1	0.580	[a]			
32	9	0.459	1.981	2.251	14	•
Behaviour					α=0.79	0.6931
9	0	0.838	0.162	3.985	4	•
4	7	0.763	0.212	2.357		
6	1	0.760	0.028	2.479		
1	1	0.748	−0.099	2.846	1	•
2	2	0.741	0.296	2.79	2	•
3	5	0.568	0.748	1.297	3	•
5	1	0.349				
Diagnosis and treatment					α=0.78	0.7426
12	7	0.797	0.34	5.472	7	•
14	2	0.745	0.624	2.146		
13	1	0.686	0.654	2.381		
11	1	0.610	−0.17	1.955	6	•
16	2	0.509	−0.942	2.288	8	•
Other people					α=0.67	1.000
8	2	0.809	−0.403	2.362	5	•
7	1	0.790	−0.491	2.299		
27	2	0.705	0.130	3.624	16	•
20	0	0.572	0.048	2.017		

[a]Item 15 prevented the program converging, this items also had a high loading on the treatment component (0.371).
Preliminary questionnaire item numbers are displayed in the first column (Table SII[1]).
2PL-ltm: 2-parameter latent trait model; BaSQoL: Basal and Squamous cell carcinoma Quality of Life questionnaire.

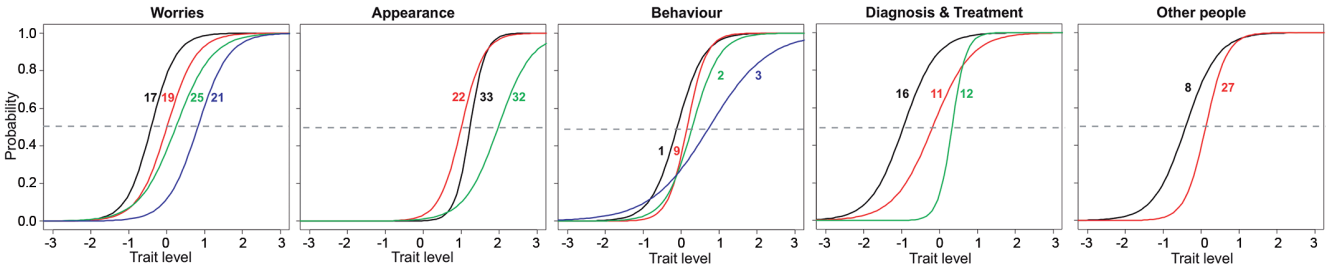

Fig. 2. Item characteristic curves of the subscales. The item characteristic curves depict the placement of the items on a latent ability and its discriminative value. For example, item 3 (provisional item number) discriminates best between patients with a high behavioural score, and item 1 discriminates best in patients with a low score. In addition, item 9 discriminates better than item 3.

was not eligible, because it had a component loading lower than 0.40.

The 5 components were labelled as: Worries (8 items, α=0.87), Appearance (7 items, α=0.84), Behaviour (7 items, α=0.85), Diagnosis & Treatment (5 items, α=0.84) and Other people (4 items, α=0.79) (**Table II**).

Item response analyses

The position on the components and discrimination values resulting from the 2PL-ltm analyses are shown in Table II. On the basis of these values the item set was reduced from 32 to 16 items. The characteristic curves of the selected items are shown in **Fig. 2**. The "Worries" and "Behaviour" subscales retained 4 items (αs 0.79–0.82), the "Appearance" and "Diagnosis & Treatment" subscales retained 3 items (αs=0.71–0.78) and the "Other people" subscale retained 2 items (α=0.67). The unidim *p*-value for the 4 selected items of "Worries" was significant ($p=0.03$), indicating that this subscale was not sufficiently unidimensional. This lack of unidimensionality was caused by item 21. However, the unidim *p*-value of all 9 items was 0.38 indicating that all 9 items (including 21) belonged to a unidimensional subscale. We decided to include the item in the final questionnaire because we considered it to be a conceptually important aspect and because of the marking of the scale of the highest position on the latent trait. Item 15 in the "Appearance" prevented the program from converging. Inspection of this item showed that it also loaded (0.37) on the "Diagnosis & Treatment" subscale, and thus violated the unidimensionality assumption. It was decided to delete this item from the analyses. After this the unidim test was insignificant for the subscales appearance, behaviour, diagnosis & treatment, and other people, indicating that the unidim assumption has been met for these subscales.

The resulting 16-item questionnaire was named the Basal and Squamous Cell Carcinoma Quality of Life (BaSQoL) questionnaire (Table SIII[1]).

Classical test theory

The 8 CTT item performance features of the newly constructed questionnaire showed that 7 out of 16 items showed only one suboptimal feature and one showed 2 suboptimal performance features (**Table III**). From a CTT perspective, the overall performance of the BaSQoL is therefore considered to be good. There was no significant correlation with the subscales of the Skindex-17 and the QLQ-C30, suggesting that different issues were captured.

Confirmatory factor analyses

Both the complete cases and the maximum likelihood with missing vales (MLMV) had acceptable to good misfit scores (RMSEA and SRMR) and good goodness of fit (CFI and TLI) (**Table IV**). The correlations between

Table III. Item performance of the Basal and Squamous cell carcinoma Quality of Life (BaSQoL) questionnaire

	BaSQoL subscales															
	Behaviour				Other people	Diagnosis & treatment			Worries				Appearance			Other people
BaSQoL item number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Item performance features																
Item difficulty																
Response distribution											•		•		•	
Item-test correlation																
Item-rest correlation																
Item discriminant validity																
Item complexity																
Internal consistency					•											•
Stepwise regression		•					•				•			•		
Provisional 33-item questionnaire number	1	2	3	9	8	11	12	16	17	19	21	25	22	32	33	27

•Indicates suboptimal performance in a given item feature. Definition of suboptimal performance in Table SI[1].
Item numbers displayed are the final BaSQoL item numbers (Table SIII[1]).

Table IV. Fit indices confirmatory factor analysis

	Complete cases	Maximum likelihood with missing values	Recommended Kline (31)	Recommended Hu & Bentler (30)	Recommended Brown (32)
Measures of misfit:					
Root mean squared error of approximation	0.050	0.053	< 0.05	± 0.06	< 0.05/< 0.08*
Standardized root mean squared residual	0.042	–	< 0.10	± 0.08	< 0.08
Goodness of fit:					
Comparative fit index	0.958	0.956	> 0.90		> 0.95
Tucker-Lewis index	0.947	0.944	> 0.90	± 0.95	> 0.95

*< 0.05: good; < 0.08 reasonable.

the subscales were generally low and there were only small differences between the 2 analyses (Table SIV[1]).

Translation

The original Dutch version of the BaSQoL was translated into English by forward-backward translation (22) (Table SIII[1]).

Scoring

The individual items are scored from 0 to 3, where 0 represents no impact and 3 very high impact. The mean score per subscale is calculated as a scale score. A minimum of 50% of the questions within the subscale have to be answered in order to calculate the subscale score. There is no total score calculated for the instrument.

DISCUSSION

The BaSQoL questionnaire was developed methodologically by following EORTC QOL group guidelines as closely as possible (20–22). It assesses the relevant dimensions of HRQoL in patients with BCC and those with SCC.

The content of the BaSQoL questionnaire has some overlap with items from the existing questionnaires for skin cancer, such as cancer recurrence or spreading, concerns about scarring, and sun behaviour. However, the BaSQoL captures a broader spectrum of the issues relevant in patients with BCC and those with SCC, such as treatment- and diagnosis-related issues and long-term behavioural changes (14, 16, 17). Since our questionnaire was developed and validated in a large Dutch patient sample, by using a population-based approach, we consider it to be representative for use in the wide range of patients with BCC and those with SCC.

Since patients were extensively involved in the whole process of development of the questionnaire, the questions are representative and are written in the terminology used by the patients.

By combining the use of modern IRT and CTT analyses we aimed to create a questionnaire with optimal psychometric properties. Therefore the BaSQoL has good face, content and construct validity.

The use of different time-frames in our questionnaire is also a unique feature. Patients noted a difference in behaviour before and after the initial diagnosis. Therefore the impact of this behavioural change is measured in the first part of the BaSQoL. The second part of the BaSQoL concerns the period of diagnosis and treatment. This, usually short, time-frame has a high impact on patients' HRQoL. This subscale is suitable for assessing the patient's experience of this specific period in order to manage anxiety during the process in case of new tumours and, in general, to optimize patient care. The final part of the questionnaire addresses the impact of the skin cancer during the past week. Since BCC and SCC are being considered as more chronic diseases, it is important to address the relevant issues at the right moment.

The preliminary validation of the BaSQoL has also been established by this study. Cronbach's αs of the reduced subscales remained reasonable, taking into account that a reduction in the number of items generally leads to a lower α (33, 34). The subscales are psychometrically robust, displaying excellent item performance and a good fit in the confirmatory factor analysis. As the BaSQoL measures different aspects of HRQoL, it showed no significant correlation with the subscales of the Skindex-17 and the QLQ-C30, confirming divergent validity. Unfortunately, none of the previously developed BCC- or SCC-specific questionnaires were included in this study because there are no validated BCC- or SCC-specific questionnaires available in Dutch and we intended to minimize respondent burden and increase the response rate. A validation study of the English version of the BaSQoL is underway. Construct validity will be addressed in this study by comparison with the validated SCI, test–retest stability and responsiveness to change. Other important features to increase interpretability, such as categorization of scores and minimally clinical important difference, remain to be determined.

Item 21 (BaSQoL, nr 11) "Were you uncertain about the future?", that violated the unidim assumption of the worries subscale, also had a suboptimal response distribution (Table III). Confirmatory factor analysis, however, showed a good fit. This item reflects a more generic aspect than the other items in the subscale, it had, by far, the highest position on the latent trait for this reason, and because of the conceptual general intent of the item we decided to keep it in the questionnaire.

In summary, the BaSQoL has good face, content and construct validity. It is representative for use in the wide

range of patients with BCC and those with SCC and captures impact on HRQoL over different time periods. The BaSQoL will therefore be a useful tool to capture impact on HRQoL in future studies.

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