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Validation of the Turkish Version of the Skin Cancer Quality of Life Impact Tool (SCQOLIT): A Health-Related Quality of Life Questionnaire for Non-metastatic Melanoma and Non-melanoma Skin Cancer

Hilayda Karakok[1], Seher Bostanci[2], Bengu Nisa Akay[2], Deniz Calıskan[3], Can Ateş[4], Kenan Köse[5]

1 Sifa Okulu, Private Practice Office of Dermatology and Venereology, Ataturk Bulvarı, Tasbası Mahallesi, Altınordu - Ordu, Turkey
2 Department of Dermatology and Venereology, Ankara University School of Medicine, Turkey
3 Department of Public Health, Ankara University School of Medicine, Turkey
4 Department of Biostatistics, Van Yüzüncü Yıl University, School of Medicine
5 Department of Biostatistics, Ankara University School of Medicine, Turkey

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Corresponding Author: Hilayda Karakok, Sifa Okulu, Private Practice Office of Dermatology and Venereology by Dr. Hilayda Karakok, Kosk Apt, no:84/A, Ataturk Bulvarı, Tasbası Mahallesi, Altınordu - Ordu, Turkey. Telephone number: 0090 0452 225 00 25 E-mail address: hk@hilaydakarakok.com

Introduction

Quality of life instruments (QoL) have been developed to measure the efficacy of treatments in chronic illnesses and cancers [1]. Skin cancers, including melanoma and non-melanoma (NMSC), are the third most common type of cancer worldwide and have been increasing in incidence [2].

There have been plenty of investigations on the QoL of patients with skin cancers and several instruments were developed [3-8]. There is only one instrument which was validated for non-metastatic skin cancers, the Skin Cancer Quality of Life Impact Tool (SCQOLIT) [9].

Numerous tools have been developed to measure QoL. Important characteristics of the tools are validity, reliability, interpretability, structure (using factor analysis or item response theory), responsiveness, interpretability, brief response burden and an acceptable administrative burden [10].

While both generic and specific tools are used to measure QoL in various types of chronic diseases, specific tools give more accurate information and may detect aspects not identified with generic tools [11].

There are two validated disease-specific QoL instruments for melanoma. The EORTC-MM was developed for metastatic melanoma. FACT-MM can assess all the stages of melanoma. Patients diagnosed with melanoma had lower emotional well-being on FACT-MM scale than normal population [12].

There are several instruments developed for the assessment of QoL of patients with NMSC. The questionnaire developed by Esser et al, was made to assess the health status of patients with basal cell carcinoma (BCC) before a surgical procedure. It is not clear whether this tool may be used to evaluate QoL and the reliability of the tool has not been investigated [13]. SCQoL was developed from a questionnaire originally developed to evaluate the QoL in patients with actinic keratosis. Only the term 'sun damage' has been changed as 'skin cancer' for this tool. It is not clear if this tool is able to measure all the aspects affected by skin cancer [14].

Facial Skin Cancer Index was developed for NMSC located on the head and neck region. The validity and reliability are well established, the instrument is designed to measure the dimensions affected by NMSC. On the other hand, it cannot be used for NMSC located anywhere but the head and neck region [5].

A specific QoL tool BasQol was developed by Waalboer-Spuijr et al. face, content and construct validation, reliability and internal consistency of BasQol was proven. The validation of the English version of BasQol is currently being searched. The tool is designed for BCC and squamous-cell carcinoma (SCC) [15].

The only validated tool which is used in non-metastatic skin cancer types is the SCQOLIT. The SCQOLIT was shown to have construct and external validation, reliability, internal consistency and responsiveness [9]. Wali et al also showed feasibility of this tool in dermatology skin cancer clinics for patients with NMSC [16].

Objectives

The objective of this study is to validate the Turkish version of the Skin Cancer Quality of Life Impact Tool (SCQOLIT) [9]).

The translation and validation of the Turkish version of the SCQOLIT provides a tool that can be used to measure QoL of NMSC in Turkish populations. The current study aims to investigate internal validation, construct validation, external validation and convergent validity, reliability and internal consistency of the Turkish version of the tool.

Methods

The study was carried out at Ankara University School of Medicine, Department of Dermatology and Venereology between December 2015 and September 2016.

The SCQOLIT was originally developed by Burdon-Jones et al to measure the QoL of patients with non-metastatic skin cancers. The permission for the translation and validation of the tool was granted by Burdon-Jones. The tool was translated into Turkish by 2 specialists in the Department of Dermatology and by a scientist of Foreign Languages Department in accordance with international translation guidelines. Three documents were created. One by the 2 specialists of Dermatology. The other two by independent translators who translated it back to English. The text was evaluated by a scientific team including a foreign linguist and a specialists of Dermatology.

A total of 141 patients who had been diagnosed and treated for skin cancer within the previous 3 months were included in this study. Patients younger than 18 years and patients with impaired cognitive functions and illiterate patients were excluded from the study.

Confirmatory factor analysis was used for the internal validation of the SCOQLIT. Comparative compliance statistics (Comparative Fit Index [CFI], Tucker-Lewis Index [TLI], Root Mean Square Error of Approximation [RMSoA]) were used to evaluate the efficacy of the model which was produced as a result of the confirmatory factor analysis.

The Dermatology Quality of Life Index (DLQI) was translated into Turkish and has been used in various studies since. The DLQI was used for external validation of the SCQOLIT. The hypothesis to be tested was whether DLQI and SCQOLIT had same directional correlations.

The SCQOLIT was tested to discriminate melanoma and NMSC to evaluate the convergent validity.

The internal consistency was assessed by using Cronbach alpha and intraclass correlation coefficient (ICC) in terms of reliability (defined by test-retest method).

Demographic characteristics of the patients and tumor characteristics were recorded to investigate their impact on QoL. Mplus trial version and SPSS 20.0 programs were used for statistical analyses.

For BCC, size and location of the tumor, primary or recurrent origin, histopathological subtype, presence or lack of perineural invasion, history of radiotherapy at the site of the tumor and immunological status of the patient were recorded to assess risk analysis. For SCC, size and location of the tumor, primary or recurrent origin, histopathological features (differentiation, tumor thickness, presence of perineural, lymphatic or vessel invasion), immunological status of the patient, history of radiotherapy and the presence of a chronic inflammation or a scar at the site of the tumor were recorded to assess the risk analysis. High risk tumor features were classified in accordance with NCCN guidelines [17]. Melanoma risk analysis was conducted in accordance with the NCCN guidelines [18]. Breslow thickness, Clark level, ulceration, presence of regression, and mitosis rate were recorded to define the stage of the melanoma.

The Ethics Committee Approval was granted (10-439-16) All the participants gave written informed consent.

Results

The mean ages were 63.75 ± 12.07, 66.53 ± 13.55, 49.24 ± 16.67 in patients with BCC (N = 65), SCC (N = 30) and melanoma (N = 46), respectively. Twenty-nine of the patients with BCC, 11 of the patients with SCC and 24 of the patients with melanoma were females (Table 1).

Patients data, number of nevi, personal and family history of skin cancer, Fitzpatrick skin type and treatment modality are shown in Table 2.

Thirty-eight BCC (N = 65) and 10 SCC (N = 30) had high risk features. Forty melanoma patients were found to be at the first stage and 6 of them were at the second stage (Table 1).

Table 1. Age, gender, risk classification of non-melanoma skin cancer and stage of melanoma

		Gender		Risk classification of non-melanoma skin cancer:	
	Mean age	Female	Male	High risk	Low risk
BCC (n=65)	63.75 ±12.07	29	36	38	27
SCC (n=30)	66.53±13.55	11	19	10	20
				Melanoma stage:	
				Stage 1	Stage 2
M (n=46)	49.24 ±16.67	24	22	40	6

Table 2. Sociodemographic features of the patients

	Number of patients	Median score of the SCOQLIT (min-max)	Mean score of the SCOQLIT ± SD
Age			
≤65	83	11 (0-28)	12.25 ± 7.038
> 65	53	6 (0-28)	7.81 ± 6.864
Gender			
Female	64	11 (0-28)	11.59 ± 7.648 SS
Male	77	9 (0-28)	9.65 ± 7.045
Number of nevi			
<100	125	9 (0-28)	10.41 ± 7.42
>100	16	10 (3-28)	11.50 ± 7.04
History of skin cancer			
Positive	108	12 (0-27)	12.36 ± 7.61
Negative	33	9 (0-28)	9.97 ± 7.22
Family history of skin cancer			
Positive	23	12.5 (0-27)	11.81 ± 8.07
Negative	119	9 (0-28)	10.52 ±7.59
Fitzpatrick skin type			
Type 1	1	17	17
Type 2	53	9 (0 - 28)	10.51 ± 7.1
Type 3	74	9 (0 - 28)	10.04 ± 7.49
Type 4	13	10 (5-28)	12.92 ± 7.79
Treatment modality			
İmiquimod	1	1	1
Cryotherapy	1	28	28
İmiquimod + excision	1	7	7
Primary excision	89	9 (0-27)	10.44 ± 7.49

Table 2 continues

Table 2. Sociodemographic features of the patients. *(continued)*

	Number of patients	Median score of the SCOQLIT (min-max)	Mean score of the SCOQLIT ± SD
Excision+ sentinell ymph node dissection	16	12 (0-28)	12.56 ± 6.59
Excision+ flap or graft procedure	27	9 (0-28)	9.26 ± 6.74
Amputation	1	7	7
Radiotherapy	2	16 (15-17)	16 ± 1.41
Vismodegib	3	9 (0-21)	10 ± 10.53

Table 3. Mean and median total score of the SCQOLIT in patients with melanoma and NMSC

	Median score of the SCOQLIT (min-max)	Mean score of the SCOQLIT ± SD
Melanoma	11 (2-28)	11.96 ± 5.94
NMSC	9 (0-28	9.84 ± 7.885

Table 4. Total Score of the SCQOLIT of patients under and above the age of 65

Age	Number of patients	Median score of the SCOQLIT (min-max)	Mean score of the SCOQLIT ± SD
≤65	83	11 (0-28)	12.25 ± 7.038
≥65	53	6 (0-28)	7.81 ± 6.864

The SCQOLIT was shown to have one dimensional structure in the original study. In the current study, the question items of the Turkish version of the SCQOLIT were assessed with confirmatory factor analysis to demonstrate tools one-dimensional structure. The compliance to the model was found to be efficient (CFI:0.952, TLI:0.938, RMSEoA:0.102). Most of the question items had a factor load greater than 0.4 except for question 3 with a factor load of 0.372, indicating the inadequacy of this question in predicting QoL, a point that the original study did not mention. Internal validity of the Turkish version of the SCQOLIT was excellent (Cronbach alpha = 0.863). Test-re-test correlation coefficient was found as high as 0.824 (%95 confidence interval 0.644 – 0.918).

The scores for SCQOLIT and DQLI were both statistically significant with same directional correlations, confirming external validity of the tool.

To test the convergent validity of the SCQOLIT, the total score of the patients with melanoma and non-melanoma skin cancer was compared. Total score of the SCQOLIT in patients with melanoma was statistically significantly higher than NMSCs indicating the tool ability to discriminate these 2skin cancer types (P = 0.024) (Table 3).

The administrative and response burden of the tool was found to be quite low as it took 2.5 to 4 minutes to respond to all the questions and the recording process of the data was easy.

The relationship between age and QoL was found to have a statistically significant negative correlation (r = -0.333, P < 0.001). Patients under the age of 65 had poorer QoL (Table 4).

There was no statistically significant relation with gender and QoL (P = 0.101). Personal and family history of skin cancer had no effect on QoL (P = 0.099, P = 0.132 respectively). There was neither statistically significant relation between Fitzpatrick skin type, the number of Nevus and QoL (P = 0.589, P = 0.536).

Furthermore, high-risk tumor characteristics in non-melanoma skin cancer and stage of melanoma had no impact on QoL (P = 0.235 for BCC, P = 1.00 for SCC, P = 0.635 for melanoma).

Conclusions

In the current study, the Turkish version of the tool was shown to have internal validation, construct validation, external validation and convergent validity, reliability and internal consistency. The factor load of question 3 was lower than 0.4 indicating the inadequacy of this term in predicting QOL. This was not investigated in the original study.

SCQOLIT is a well-established tool in terms of internal validation, construct validation, external validation and convergent validity, reliability, internal consistency and feasibility [9,16].

The mean scores of SCQOLIT of the patients with melanoma were similar in both the current and the original study. On the other hand, the mean scores (mean = 9, range 0-28) of the SCQOLIT of patients with NMSC in the current study was higher than those in the original study (mean = 4, range 0-19)].

The percentage of patients with SCC in the present study was 31.6% whereas it was 10% in the original study. Additionally, 58.4% of all BCCs had high risk features in the current study. The original study did not mention the risk classification and the percentage of the high-risk tumors in their population [9]. These findings might be related with the differences between populations.

In terms of factors that might impact SCQOLIT scores in current study was age. Age was shown to be the only factor having a statistically significant impact on SCQOLIT. There was a negative correlation between age and the scores. Patients under the age of 65 had poorer QoL. The lower median age of the study population in the current study compared with the original study might be the explanation of this result. El Abbadi et al also found a negative correlation between skin cancer and patients age, gender and location of the tumor [19]. While similar results were also observed in the literature, some investigators found no relation between age and QOL [20-25].

There was no statistically significant relation between previous skin cancer history and QoL in the present study. Rhee et al found that in patients with NMSC the history of previous skin cancer had a negative impact on QOL in contrast to Steinbauer et al who observed no relation [24,25].

Current study has a very limited number of patients with melanoma, and findings showed no relation between QoL and a positive family history of melanoma. Barbato et al found that patients with melanoma who had a positive family history of melanoma had better QoL scores [26].

Both the current study and the original study found no relationship between Melanoma Breslow Thickness and QoL while Holterhouse et al observed that the stage of the tumor (stage 0-2) had a negative impact on QOL [9,27]. We found no relation between Fitzpatrick skin type or high-risk tumor features and QoL in the current study.

As the current study aimed to validate the Turkish version of the SCQOLIT, the sample size was too small (not large enough) to investigate and demonstrate the relation between QoL and age, Fitzpatrick skin type, personal or family history of skin cancer, stage or high-risk tumor features. This was the main limitation of the study. Further studies with larger patient groups and repeated SCQOLIT in defined timeframes could be planned to investigate the relation between age and QoL.

In conclusion, the translation and validation of the Turkish version of the SCQOLIT provides a valid tool that can be used to measure QoL of non-metastatic skin cancers in Turkish- speaking populations. This tool can be used to investigate QoL and many parameters mentioned above in further studies.

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