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Validation of the Polish version of the EORTC Head and Neck module (QLQ-H&N35)

Walidacja polskiej wersji językowej kwestionariusza EORTC QLQ-H&N35

Aim. The aim of this study was to psychometrically validate the EORTC translated, Polish version of the EORTC QLQ-H&N35 questionnaire to support using it in the Polish clinical setting in patients with head and neck malignancies.

Materials and Methods. Patients with histologically confirmed head and neck malignancies were included in the study. All patients filled in the Polish version of the EORTC QLQ-C30, the EORTC QLQ-H&N35 module, and a demographic questionnaire. Standardized validity and reliability analyses were performed.

Results. During the recruitment period a total of 176 patients (82 females - 46.6%) were enrolled into the study, with a mean age of 54.3±11.2 years. Cronbach alpha values ranged from 0.71 to 0.87. Satisfactory convergent and discriminant validity in multi-trait scaling analyses was seen.

Conclusions. The Polish version of the EORTC QLQ-H&N35 module is a reliable and valid tool for measuring HRQoL in Polish patients with head and neck malignancies. It can be fully recommended for use in the Polish clinical setting.

Cel. Celem badania była walidacja psychometryczna, przetłumaczonej przez EORTC, polskiej wersji językowej kwestionariusza EORTC QLQ-H&N35, aby dostarczyć danych niezbędnych do wsparcia jego wykorzystania w codziennej pracy klinicznej z chorymi na nowotwory głowy i szyi.

Materiały i Metody. Do badania włączani byli pacjenci z histologicznym rozpoznaniem nowotworu okolicy głowy i szyi. Wszyscy zostali poproszeni o uzupełnienie kwestionariuszy EORTC QLQ-C30, EORTC QLQ-H&N35 oraz krótkiego kwestionariusza demograficznego. Dane zostały przeanalizowane za pomocą odpowiednich testów statystycznych.

Wyniki. Do badania włączono 176 pacjentów (82 kobiety – 46.6%) w średnim wieku 54.3±11.2 lat. Wartości alfy Cronbach'a dla poszczególnych skal kwestionariusza mieściły się w przedziale 0.71-0.87, spełniając założone kryteria. Ponadto, w pozostałych ocenach, kwestionariusz EORTC QLQ-H&N35 wykazał się zadowalającymi właściwościami psychometrycznymi.

Wnioski. Polska wersja językowa kwestionariusza EORTC QLQ-H&N35 jest narzędziem o odpowiednich właściwościach psychometrycznych, pozwalający na rzetelną ocenę jakości życia pacjentów z nowotworami okolicy głowy i szyi. Może on być z powodzeniem wykorzystywany w codziennej pracy klinicznej z tą grupą chorych.

Introduction

Worldwide, the incidence and mortality of head and neck neoplasms is increasing [1], with head and neck cancers amounting to about 12% of all cancer types [2]. The first person to ever mention a head and neck tumor in writing was probably Hippocrates who described a naso-pharynx fibroma.

Patients with head and neck malignancies have to cope not only with the total impact of the disease itself but also its treatment and related side-effects, which can have tremendous impact on aspects of daily living such as eating, swallowing, breathing, and communication [3]. Connected with this is the rising concern about the use of health-related quality of life (HRQoL) measures to

assess this important outcome in oncology. Patients with head and neck malignancies have their well-being greatly affected both through the disease it's treatment and the outcomes of both those factors [4].

Pretherapeutic staging protocols as well as the management that is selected produce dysfunction, disfigurement, and substantial disability even after successful curative treatment. Successful medical results often coexist with unsatisfactory outcomes from the patient's point of view [5,6].

Outcomes which are most commonly used in oncological practice include, among others, overall survival, disease-free survival, and time to disease progression. Although the mentioned outcomes (the so

called “hard endpoints”) are essential in oncological practice, there is widespread consensus that these should be supplemented by tools able to measure HRQoL [7], and thus produce additional “soft endpoints”. In response to this need, several specific instruments for patients with head and neck malignancies have been developed and are currently commonly used in practice as well as in clinical trials. These include the European Organization for Research and Treatment of Cancer (EORTC) core questionnaire (QLQ-C30) [8, 9] with its head and neck module (QLQ-H&N35) [10, 11], and Functional Assessment of Cancer Therapy - Head and Neck (FACT-H&N) [12].

The European Organization for Research and Treatment of Cancer Quality of Life Group (QLG) has developed a series of questionnaires to assess the HRQoL of cancer patients – both for use in clinical trials, as well as in everyday clinical practice. The EORTC QLG system basis on a single core questionnaire (the QLQ-C30) [10] which is used to measure the “common” part of HRQoL of all cancer patients. This tool is then supplemented with site-specific modules which are meant to measure HRQoL aspects specific for a certain cancer type, for example head and neck malignancies [10, 11]. The EORTC QLQ-H&N35 module has been translated into 19 languages (including Polish), widely tested and used in a multitude of clinical trials [6,7,10,11,13,14]. However, over the years, several studies have pointed out that the EORTC QLQ-H&N35 might benefit from updating, for example, to reduce the relatively high percentage of missing values on the speech and sexuality scale, or to improve the internal consistency of the speech scale [15]. That is why the EORTC is currently running a study aimed at updating the EORTC QLQ-H&N35 [16]. However, as many clinical trials that are currently running, continue to use the EORTC QLQ-H&N35, it is well needed to possess a validated Polish language version of this module, to allow for the inclusion of Polish head and neck cancer patients into those trials that measure HRQoL using the EORTC tool.

That is why the aim of our study was to validate the EORTC translated, Polish version of the EORTC QLQ-H&N35 questionnaire, and to show that this tool is an acceptable and psychometrically robust measure to collect HRQoL data in Polish patients with head and neck malignancies. Our group has previously carried out a preliminary validation of the Polish language version of the EORTC QLQ-H&N35 [11], and has experience in performing this kind of validation studies [17-19].

Materials and Methods

Patients

The patients were prospectively recruited between January 2013 and September 2015 in three hospitals in Krakow, Poland.

Patients were eligible if they were above 18 years old and had histological confirmation of a cancer of the head and neck region. Exclusion criteria were lack of consent to participate in the study and inability to understand or complete the questionnaires. The patients included were classified into

groups based on their current Karnofsky Performance Status (KPS) (>80 or ≤ 80) and being on or off treatment [10,20].

Interview procedure

The patients were approached during their visits at the outpatient clinics of the participating centres or during their stay at the clinic, and informed about the study. They were interviewed only after written informed consent was obtained. Each patient completed the Polish version of the EORTC QLQ-C30, the EORTC QLQ-H&N35 module and a short questionnaire on demographic data. Patients were provided the measures before undergoing planned treatment. The questionnaires were administered by a medical doctor or a trained study nurse.

During the interview process, assistance was offered if the patient did not have his/hers reading glasses available. In such a case the interviewer would read the questions out loud to the patient. Interpreting questions or providing suggestions from the side of the interviewer was strictly forbidden [21].

Questionnaires

The EORTC QLQ-C30 is a 30-item questionnaire comprised of a global health status, five multi-item functional scales, three multi-item symptom scales and six symptom single items. It is translated into over 85 languages [13,22], and validated in most of its language versions, including Polish [9].

The EORTC QLQ-H&N35 is a 35-item cancer-specific module composed of 18 domains, including seven multi-item scales that assess pain (questions 1-4), swallowing (questions 5-8), sense problems (questions 13 and 14), speech (questions 16, 23, 24), social eating (questions 19-22), social contact (questions 18, 25-28), and sexuality (questions 29 and 30). It also includes 11 single items - teeth (no. 9), opening mouth (no. 10), dry mouth (no. 11), sticky saliva (no. 12), coughing (no. 15), feeling ill (no. 17), pain killers (no. 31), nutritional supplements (no. 32), feeding tube (no. 33), weight loss (no. 34), and weight gain (no. 35). All 18 domains of the QLQ-H&N35 have standardized scores ranging from 0 to 100, with higher scores indicating a greater degree of symptoms (worse HRQoL) [10,11].

All of the EORTC QLQ-C30 and the EORTC QLQ-H&N35 multi-item scales and single items are scored on a 1- to 4-point Likert scale (‘not at all’, ‘a little’, ‘quite a bit’, ‘very much’), apart from items 29 and 30 of the EORTC QLQ-C30, which are scored on a 1- to 7-point scale. Detailed information on how to score the EORTC questionnaires can be found in the EORTC QLQ-C30 scoring manual and its addendum [23]. The questionnaire and the scoring manual were obtained from the EORTC Quality of Life Department, upon request of the main author of the study.

Statistical analysis

Several pre-planned standard psychometric tests were conducted. These approaches can be seen in the EORTC Module Development Guidelines [24,25].

Scoring of the two questionnaire followed the standard EORTC scoring instructions. Scores for single items and multi-item functional and symptom scales were calculated by linear transformation of raw scores into a 0–100 score, with 100 representing best global health, functional status or worst symptoms – depending on the measuring property of each multi-item or single-item scale, as described by the EORTC Scoring Manual [23]. To analyse the data descriptive statistics (mean, standard deviation, percentage distribution) were used.

Convergent validity was assessed by correlating each item with its own scale. Discriminant validity was assessed by correlating each item with any other scale. Evidence of item convergent validity was defined as a correlation of 0.40 or greater between an item and its own scale (corrected for overlap). A scaling success for an item was seen when the correlation between an item and its own scale was significantly higher than its correlation with other scales [26]. Cronbach’s alpha coefficient was calculated to assess the internal consistency of the Polish version of the EORTC QLQ-H&N35. Internal consistency estimates of a magnitude of >0.70 were considered acceptable for group comparisons [26].

Clinical validity was assessed using the Wilcoxon rank sum nonparametric test. This assesses if the questionnaire was able to discriminate between subgroups of patients differing in clinical status. Known-groups used in this study were based on Karnofsky Performance Status (KPS) and being on or off treatment. Differences between groups were tested with the Mann–Whitney test.

A subset of randomly chosen (based on a computer generated algorithm) patients completed the questionnaires twice ($n = 40$) for test–retest evaluation. Test–retest reliability of the EORTC QLQ-H&N35 was assessed using interclass correlations (ICC) between baseline and retest 2 weeks later. A correlation of >0.80 was considered ‘good’ [26].

Spearman correlation analysis was performed to explore the relationship between scales of the EORTC QLQ-C30 and the EORTC QLQ-H&N35. This was done to assess whether and to what extent clinical overlapping existed between the EORTC QLQ-C30 and the EORTC QLQ-H&N35 scales.

Study sample size was based on the proposal of Tabachnick and Fidell [27], which states that in order to obtain reliable estimates through multivariate analysis, the number of observations should be 5–10 times the number of variables in the model.

The significance level was set at $p < 0.05$. Statistical analysis was conducted using computer software Statistica 10.0 PL by StatSoft Poland (licensed to the Jagiellonian University Medical College).

The acceptability of the QLQ-H&N35 was assessed by the response rate, percentage of missing data, assistance and time needed to complete the questionnaire and details of items considered upsetting, confusing or difficult in the questionnaire.

Ethics

The research protocol was approved by

the Jagiellonian University Ethics Committee (registry number KBET/7/B/2013). The study has been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

Results

Patient characteristics and acceptability

During the recruitment period a total of 176 patients (82 females - 46.6%) were enrolled into the study, with a mean age of 54.3±11.2 years. Patients' clinical and demographic data are presented in Table I.

Fifteen of the patients (8.5%) that were approached refused to participate in the study. The main reason for refusing to participate was lack of time and will to fill in the questionnaires.

All 176 patients answered both the EORTC QLQ-C30 and the EORTC QLQ-

-H&N35. Only 4.9% of item responses were missing.

As much as 55.7% of the interviewees required assistance completing the questionnaires. The main reasons for requiring help were lack of reading glasses (over 80% of the patient sample requiring help). The total time for completion of the questionnaires and interview was approximately 16 minutes without assistance and 28 with assistance. No patients reported the questions to be upsetting.

Clinical history and physical examination were registered for all patients from patient files.

Reliability and validity

Reliability, convergent and discriminant validity of QLQ-H&N35 multi-item scales are presented in Table II.

Taking into account the EORTC QLQ-H&N35 its own-scale correlations were considered good. All item correlations within their own scales exceeded the 0.40 criterion, and were correlated higher with their own scale than with the other scales. All presented Cronbach alpha values exceeded the 0.7 criterion.

Clinical validity assessment by known-group comparison is presented in Table III. There were significant differences between

the groups in most of the EORTC QLQ-H&N35 scales and items.

A fairly good correlation between theoretically linked scales and a low correlation between independent scales was found [Tab. IV].

For test-retest assessment ICC was used. The ICC's for the EORTC QLQ-H&N35 ranged from 0.82 to 0.90, and were considered to be 'good'.

Discussion

As mentioned in the introduction, head and neck malignancies are a major health problem worldwide, including Poland. The traditional risk factors for those types of cancer include smoking tobacco and consuming alcohol [28], two still very prevalent habits of the Polish society [29].

Currently it is necessary to complement classical oncologic outcomes with the use of measures of patients' perception on disease impact and treatment consequences. There exists general agreement in the literature that measuring HRQL can achieve this aim [6].

The Polish translation of the EORTC QLQ-H&N35 has been with us for the past 12 years, and has been used in several studies [30,31]. However, up-to-date no proper, complete psychometric validation has been

Table I
Patients' clinical and demographic data.
Kliniczne i demograficzne dane pacjentów.

Variable	Overall n=176
Age (mean±SD)	54.3±11.2
Education (%)	
Elementary	35 (19.9%)
High School	94 (53.4%)
University	47 (26.7%)
Current working status (%)	
Employed	39 (22.2%)
On sick leave	81 (46.0%)
Unemployed	9 (5.1%)
Retired/Pensioner	47 (26.7%)
Living (%)	
Alone	44 (25.0%)
With partner or family	111 (63.1%)
With others	21 (11.9%)
Marital status (%)	
Married	125 (71.0%)
Widowed	29 (16.5%)
Divorced	13 (7.4%)
Single	9 (5.1%)
Tumour type (%)	
Squamous cell	149 (84.7%)
Adenocarcinoma	27 (15.3%)
Treatment (%)*	
Surgery	141 (80.1%)
Chemotherapy	31 (17.6%)
Radiotherapy	45 (25.6%)
Active treatment (%)	
Yes	94 (53.4%)
No	82 (46.6%)
Karnofsky Performance Status (%)	
>80	137 (77.8%)
≤80	39 (22.2%)

* - more than one treatment option per patient possible; SD - standard deviation.

Reliability, convergent and discriminant validity of QLQ-H&N35 multi-item scales.

Table II
Reliability, convergent and discriminant validity of QLQ-H&N35 multi-item scales.
Wiarygodność oraz trafność zbieżna i rozbieżna skal QLQ-H&N35.

EORTC QLQ-H&N35 multi-item scale	Convergent validity ¹	Discriminant validity ²	Cronbach's alpha
Pain	0.51-0.72	0.07-0.40	0.84
Swallowing	0.51-0.85	0.10-0.37	0.81
Senses Problems	0.35-0.79	0.05-0.31	0.82
Speech Problems	0.44-0.70	0.12-0.39	0.80
Trouble with Social Eating	0.56-0.78	0.19-0.45	0.87
Trouble with Social Contact	0.31-0.51	0.07-0.28	0.77
Less Sexuality	0.35-0.53	0.05-0.36	0.71

SD - standard deviation; ¹ - Item-own scale correlation, Spearman correlation coefficient, corrected for overlap
² - Item-other scale correlation, absolute values displayed, Spearman correlation coefficient.

Table III
EORTC QLQ-H&N35 known group comparison.
Porównanie znanych grup EORTC QLQ-H&N35.

EORTC QLQ-H&N35	On Treatment (n=94)	Off Treatment (n=82)	p-value	KPS>80 (n=137)	KPS≤80 (n=39)	p-value
Multi-item scales						
Pain	28.5 (13.7)	23.0 (22.5)	0.049	15.1 (12.0)	31.7 (14.9)	<0.0001
Swallowing	32.1 (15.9)	10.5 (14.1)	<0.0001	16.6 (13.1)	29.4 (19.0)	<0.0001
Senses Problems	26.4 (17.9)	15.1 (13.2)	<0.0001	18.5 (23.3)	22.6 (17.1)	0.31
Speech Problems	31.1 (23.9)	30.0 (20.7)	0.75	17.2 (11.8)	26.5 (19.3)	0.0003
Trouble with Social Eating	41.3 (29.7)	18.2 (23.1)	<0.0001	19.9 (21.3)	33.2 (24.4)	0.0011
Trouble with Social Contact	40.5 (25.6)	15.4 (16.3)	<0.0001	12.6 (11.2)	29.5 (17.4)	<0.0001
Less Sexuality	45.9 (27.2)	29.5 (15.2)	<0.0001	14.2 (9.1)	40.6 (21.7)	<0.0001

KPS - Karnofsky Performance Score; Values expressed as mean and standard deviation. Statistically significant differences are marked in bold.

Table IV

Correlations between scales of the EORTC QLQ-C30 and the EORTC QLQ-H&N35.

Korelacje pomiędzy skalami EORTC QLQ-C30 i EORTC QLQ-H&N35.

	GHS	PF	RF	EF	CF	SF	FA	NV	PA	HNPA	HNSW	HNSE	HNSP	HNSO	HNSC
GHS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
PF	0.49	-	-	-	-	-	-	-	-	-	-	-	-	-	-
RF	0.51	0.44	-	-	-	-	-	-	-	-	-	-	-	-	-
EF	0.47	0.13	0.30	-	-	-	-	-	-	-	-	-	-	-	-
CF	0.50	0.42	0.49	0.35	-	-	-	-	-	-	-	-	-	-	-
SF	0.32	0.10	0.25	0.54	0.35	-	-	-	-	-	-	-	-	-	-
FA	-0.55	-0.59	-0.52	-0.49	-0.59	-0.20	-	-	-	-	-	-	-	-	-
NV	-0.24	-0.33	-0.03	-0.15	-0.26	-0.29	0.20	-	-	-	-	-	-	-	-
PA	-0.44	-0.30	-0.41	-0.41	-0.35	-0.33	0.52	0.20	-	-	-	-	-	-	-
HNPA	-0.30	-0.16	-0.27	-0.37	-0.17	-0.18	0.15	0.25	0.52	-	-	-	-	-	-
HNSW	-0.27	-0.27	-0.25	-0.30	-0.33	-0.25	0.37	0.07	0.40	0.37	-	-	-	-	-
HNSE	-0.34	-0.13	-0.29	-0.14	-0.18	-0.37	0.10	0.02	0.15	0.11	0.02	-	-	-	-
HNSP	-0.16	-0.20	-0.15	-0.16	-0.09	-0.40	0.03	0.10	0.08	0.05	-0.04	0.59	-	-	-
HNSO	-0.38	-0.22	-0.37	-0.31	-0.29	-0.19	0.34	0.05	0.45	0.55	0.45	0.19	0.03	-	-
HNSC	-0.43	-0.40	-0.43	-0.39	-0.40	-0.45	0.30	0.26	0.41	0.19	0.19	0.41	0.60	0.26	-
HNSX	-0.30	-0.36	-0.32	-0.10	-0.25	-0.26	0.28	0.02	0.12	0.21	0.11	0.40	0.17	0.20	0.44

Correlation coefficients higher than 0.40 are marked in bold

EORTC QLQ-C30: GHS - global quality of life; PF - physical functioning; RF - role functioning; EF - emotional functioning; CF - cognitive functioning; SF - social functioning; FA - fatigue; NV - nausea & vomiting; PA - pain.

EORTC QLQ-H&N35: HNPA - pain; HNSW - swallowing; HNSE - senses; HNSP - speech; HNSO - social eating; HNSC - social contact; HNSX - sexuality.

performed. To-date our group has only performed a short preliminary study [11] aiming at the validation of the EORTC QLQ-H&N35. This was done to show that the QLQ-H&N35 can be used in clinical practice as well as in research, so that the ongoing studies using the EORTC QLQ-H&N35 had a justifiable basis that the Polish version of this questionnaire is actually psychometrically robust. Thus, the aim of the current study was to report the final validation data on the EORTC translated Polish version of the EORTC QLQ-H&N35 questionnaire.

Currently in oncology new treatment options arise at an intensified pace [32]. It is imperative to remember that HRQoL should always accompany survival. Thus, there exists a strong need for up-to-date and precise tools that will be able to accurately assess HRQoL in cancer patients, including those with head and neck malignancies. One of the major drawbacks of some of the clinical trials that have been performed in the last years is the fact that they either decided not to include HRQoL as one of their endpoints or used simple, generic questionnaires to assess HRQoL in specific patient groups. The EORTC QLQ-H&N35 seems to perfectly fill this gap for the head & neck cancer patient population.

An important part of our study was that the participation rejection rate was below 10% showing the acceptability of the measures for Polish patients. This was further backed by the fact that only 5% of the item responses were missing.

The fact that over half of the patients required assistance filling in the questionnaires might arise not only from the simple lack of reading glasses (the case in most patients) but also from the fact that patients have a need for more direct contact with physicians and perceived this study as an

opportunity to talk more with their medical professionals.

As in the original study by Bjordal et al. [10] construct analysis of the EORTC QLQ-H&N35 confirmed the presence of seven distinct multi-item scales, in which items within each scale were highly correlated with one another compared with items from other scales. Instrument validity indicates how an instrument can capture what it intends to measure. The results of our study have shown the validity of the Polish version of the EORTC QLQ-H&N35 through meeting the necessary standard of item convergent and discriminant validity.

Reliability of a questionnaire describes how consistent in scoring between different assessment the tool is. The two most commonly used indicators of a questionnaires reliability are test-retest reliability and Cronbach's α (internal consistency). For the Polish translation of the EORTC QLQ-H&N35 all presented Cronbach alpha values exceeded the assumed 0.7 criterion. The results of test-retest analysis were considered to be "good" also exceeding the assumed criterion of 0.8.

The results of the known-group comparison demonstrated that the EORTC QLQ-H&N35 module is able to accurately discriminate between patient subgroups differing in clinical status. Overall the obtained results closely resemble to the original study of Bjordal et al. [10].

The main limitation of this study stemmed from its design, and related to the lack of the possibility to measure responsiveness over time. The setup of the interview procedure precluded us from assessing the patients at several time-points, and was limited only to the test-retest analysis. However, we did not anticipate to obtain significant differences from the original study [10] in

regards to responsiveness over time, and thus assume that the results using the Polish language version of the questionnaire would be similar.

Conclusions

In conclusion the Polish version of the EORTC QLQ-H&N35 module is a reliable and valid tool for measuring HRQoL in patients with head and neck malignancies. Further research in regards to responsiveness over time of the EORTC QLQ-H&N35 would be beneficial, however the lack of this parameter in regards to the Polish translation does not preclude the use of this tool in the Polish clinical setting.

Conflict of Interest

None declared.

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