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## PRELIMINARY PSYCHOMETRIC VALIDATION OF THE POLISH VERSION OF THE EORTC HEAD AND NECK MODULE (QLQ-H&N35)

**Abstract:** Aim: The aim of our study was to report preliminary validation data on the EORTC translated, Polish version of the EORTC QLQ-H&N35 questionnaire to show that this tool is an acceptable and psychometrically robust measure to collect HRQoL data in Polish patients with head and neck malignancies.

**Materials and Methods:** Patients with histological confirmation of head and neck malignancies were eligible for the study. All patients filled out the Polish version of the EORTC QLQ-H&N35 module in addition to EORTC QLQ-C30 and a demographic questionnaire. Standardized validity and reliability analyses were performed.

**Results:** Fifty-one patients (23 females — 45.1%) were enrolled into the study, with a mean age of  $51.3 \pm 12.9$  years. Cronbach alpha coefficients, range 0.72–0.85, showed positive internal consistency. Satisfactory convergent and discriminant validity in multi-trait scaling analyses was seen.

**Conclusions:** Basing on the preliminary data from this report, one can say that 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. However further research is needed to establish the full psychometric properties of the described module, especially test-retest and responsiveness over time.

**Key words:** psychometric; validation; head & neck; H&N35; EORTC.

### INTRODUCTION

Worldwide, the incidence and mortality of head and neck neoplasms is increasing [1]. Currently, there is a rising concern about the use of health-related quality of life (HRQoL) tools to assess this important outcome in oncology. This is especially so in patients with head and neck malignancies, because they greatly affect one's well-being [2]. 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 [3, 4].

Traditionally, cancer outcomes are measured in terms of overall survival, disease-free survival, time to disease progression, and other prognosis outcomes.

Although these outcomes remain essential, there is general recognition of the need to assess the impact of cancer and its treatment on patient's HRQoL [5]. In response to this need, several specific instruments for patients with head and neck malignancies have been developed and are commonly used in practice as well as in clinical trials, including the European Organization for Research and Treatment of Cancer (EORTC) core questionnaire (QLQ-C30) [6–8], its head and neck module (QLQ-H&N35) [9], and Functional Assessment of Cancer Therapy — Head and Neck (FACT-H&N) [10].

The aim of our study was to report preliminary validation data on the EORTC translated, Polish version of the EORTC QLQ-H&N35 questionnaire 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 previous experience in performing this kind of validation studies [11].

## MATERIALS AND METHODS

### PATIENTS

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

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.

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 included 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  $\leq 80$ ) and being on or off treatment [9, 12].

### 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 questionnaire concerning demographic data. Patients were provided the measures before undergoing planned treatment. The questionnaires were administered by a medical doctor.

## 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 [8, 13]. This is one of the most frequently used HRQoL measures reported in clinical trials [14].

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) [4, 5, 9].

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 [15]. 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 [16, 17].

Scoring of the two measures followed the standard EORTC scoring instructions. Specifically, 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 [15]. 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 [18]. 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 [18].

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.

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.

## RESULTS

### PATIENT CHARACTERISTICS AND ACCEPTABILITY

During the 5 month recruitment period a total of 51 patients (23 females — 45.1%) were enrolled into the study, with a mean age of  $51.3 \pm 12.9$  years. Patients' clinical and demographic data are presented in Table 1.

No patients refused to participate in the study. All 51 patients answered both the EORTC QLQ-C30 and the EORTC QLQ-H&N35. Only 2.4% of item responses were missing.

As much as 43% of the interviewees required assistance completing the questionnaires. The total time for completion of the questionnaires and interview was approximately 19 minutes without assistance and 26 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 2.

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.

Table 1

Patients' clinical and demographic data.

| Variable                         | Overall n = 51 |
|----------------------------------|----------------|
| Age (mean±SD)                    | 51.3 ± 12.9    |
| Education (%)                    |                |
| Elementary                       | 7 (13.7%)      |
| High School                      | 36 (70.6%)     |
| University                       | 8 (15.7%)      |
| Current working status (%)       |                |
| Employed                         | 29 (56.9%)     |
| Unemployed                       | 4 (7.8%)       |
| Retired/Pensioner                | 18 (35.3%)     |
| Living (%)                       |                |
| Alone                            | 8 (15.7%)      |
| With partner or family           | 41 (80.4%)     |
| With others                      | 2 (3.9%)       |
| Marital status (%)               |                |
| Married                          | 41 (80.4%)     |
| Divorced                         | 6 (11.8%)      |
| Single                           | 4 (7.8%)       |
| Tumour type (%)                  |                |
| Squamous cell                    | 40 (78.4%)     |
| Adenocarcinoma                   | 11 (21.6%)     |
| Treatment (%)*                   |                |
| Surgery                          | 47 (92.2%)     |
| Chemotherapy                     | 8 (15.7%)      |
| Radiotherapy                     | 14 (27.5%)     |
| Active treatment (%)             |                |
| Yes                              | 39 (76.5%)     |
| No                               | 12 (23.5%)     |
| Karnofsky Performance Status (%) |                |
| >80                              | 36 (70.6%)     |
| ≤80                              | 15 (29.4%)     |

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

Table 2

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

| EORTC QLQ-H&N35 multi-item scale | Convergent validity <sup>1</sup> | Discriminant validity <sup>2</sup> | Cronbach's alpha |
|----------------------------------|----------------------------------|------------------------------------|------------------|
| Pain                             | 0.53–0.69                        | 0.04–0.42                          | 0.81             |
| Swallowing                       | 0.51–0.82                        | 0.08–0.33                          | 0.80             |
| Senses Problems                  | 0.42–0.83                        | 0.02–0.29                          | 0.83             |
| Speech Problems                  | 0.39–0.61                        | 0.14–0.36                          | 0.77             |
| Trouble with Social Eating       | 0.55–0.71                        | 0.21–0.48                          | 0.85             |
| Trouble with Social Contact      | 0.33–0.49                        | 0.09–0.22                          | 0.79             |
| Less Sexuality                   | 0.40–0.51                        | 0.01–0.38                          | 0.72             |

SD — standard deviation

<sup>1</sup> — Item-own scale correlation, Spearman correlation coefficient, corrected for overlap<sup>2</sup> — Item-other scale correlation, absolute values displayed, Spearman correlation coefficient

Clinical validity assessment by known-group comparison is presented in Table 3. There were significant differences between the groups in most of the EORTC QLQ-H&N35 scales and items.

Table 3

EORTC QLQ-H&amp;N35 known group comparison.

| EORTC QLQ-H&N35             | On Treatment (n = 39) | Off Treatment (n = 12) | p-value      | KPS>80 (n = 36) | KPS≤80 (n = 15) | p-value           |
|-----------------------------|-----------------------|------------------------|--------------|-----------------|-----------------|-------------------|
| <i>Multi-item scales</i>    |                       |                        |              |                 |                 |                   |
| Pain                        | 23.2<br>(19.4)        | 24.5<br>(20.1)         | 0.84         | 12.3<br>(9.3)   | 28.1<br>(17.4)  | <b>&lt;0.0001</b> |
| Swallowing                  | 30.6<br>(18.1)        | 11.4<br>(13.2)         | <b>0.001</b> | 14.7<br>(12.3)  | 24.8<br>(19.0)  | <b>0.028</b>      |
| Senses Problems             | 20.0<br>(12.5)        | 17.9<br>(14.2)         | 0.62         | 17.3<br>(17.1)  | 19.1<br>(18.7)  | 0.74              |
| Speech Problems             | 28.7<br>(21.5)        | 26.3<br>(18.7)         | 0.73         | 15.4<br>(14.2)  | 22.3<br>(21.1)  | 0.18              |
| Trouble with Social Eating  | 38.4<br>(27.0)        | 18.9<br>(22.4)         | <b>0.028</b> | 19.4<br>(18.0)  | 28.6<br>(19.7)  | 0.11              |
| Trouble with Social Contact | 37.3<br>(24.6)        | 16.1<br>(10.1)         | <b>0.006</b> | 14.3<br>(15.6)  | 26.3<br>(21.5)  | <b>0.030</b>      |
| Less Sexuality              | 41.7<br>(23.9)        | 32.6<br>(16.6)         | 0.23         | 11.4<br>(10.6)  | 38.8<br>(24.9)  | <b>&lt;0.0001</b> |

Values presented as mean±SD; KPS — Karnofsky Performance Status; SD — standard deviation (given in brackets); Statistically significant values shown in bold.

## DISCUSSION

There is a need to complement classical oncologic outcomes with the use of measures of patients' perception on disease impact and treatment consequences. There exists general agreement in literature that measuring HRQoL can achieve this aim [4].

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 [19, 20]. However, up-to-date no proper psychometric validation has been performed. Thus, the aim of our study was to report preliminary validation data on the EORTC translated Polish version of the EORTC QLQ-H&N35 questionnaire. The full study, aiming to deliver complete QLQ-H&N35 psychometric data, is underway. However, to show that the QLQ-H&N35 can be used in clinical practice as well as in research, we decided to publish this preliminary report.

As new treatment options arise, it is imperative to remember that HRQoL should always accompany survival. Thus the need for elegant instruments able to accurately assess HRQoL in cancer patients, including those with head and neck malignancies. A major drawback of some of the clinical trials that have been performed is the fact that they either omitted HRQoL assessment or used generic questionnaires to assess HRQoL in specific patient groups. The EORTC QLQ-H&N35 seems to perfectly fill the gap.

An important part of our study was that none of the 51 patients approached declined to complete the HRQoL forms. Therefore, this can be seen as an indicator of the acceptability of the measures for Polish patients. The fact that almost half of the patients required assistance filling in the questionnaires might arise 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. [9] 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.

The results of the known-group comparison demonstrated that the EORTC QLQ-H&N35 module is able to discriminate between patient subgroups differing in clinical status. Overall the obtained results are partially similar to the original study [9] and to the study by Carrillo et al. [4].

The main limitation of this study is of course the small number of participants. However, the full study is underway, and the target sample size is carefully planned according to the proposal of Tabachnick and Fidell [21]. It 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. Another limitation is the fact that responsiveness over time and test-retest were not analyzed. This will also be calculated, once the target sample size is reached.

Clinical trials including HRQoL outcomes provide invaluable information concerning the effects of medical management. However, there is controversy about whether HRQL data contribute significantly to the clinical decision making process. This phenomenon may be due to difficulties in understanding HRQL facts by patients or physicians. Recent research is focusing on strategies to increase physician and patient understanding of HRQL information, which is usually complex as a result of its multifactorial nature [22].

## CONCLUSIONS

In conclusion, basing on the preliminary data from this report, one can say that 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. However further research is needed to establish the full psychometric properties of the described module, especially test-retest and responsiveness over time.

## CONFLICT OF INTEREST

None declared.

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