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## Original Paper

# The EORTC Core Quality of Life Questionnaire (QLQ-C30): Validity and Reliability When Analysed With Patients Treated With Palliative Radiotherapy

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**The EORTC Core Quality of Life questionnaire (EORTC QLQ-C30) is designed to measure cancer patients' physical, psychological and social functions. The questionnaire is composed of multi-item scales and single items. 247 patients completed the EORTC QLQ-C30 before palliative radiotherapy and 181 after palliative radiotherapy. The questionnaire was well accepted with a high completion rate in the present patient population consisting of advanced cancer patients with short life expectancy. In addition, the questionnaire was found to be useful to detect the effect of palliative radiotherapy over time. The scale reliability was excellent for all scales except the role functioning scale. Excellent criterion validity was found for the emotional functioning scale where it was correlated with GHQ-20. Performance of the questionnaire was improved after the second evaluation as compared with the first. The present study shows that the EORTC QLQ-C30 is found to be practical and valid in measuring quality of life in patients with advanced disease.**

**Key words: quality of life, palliative radiotherapy, EORTC QLQ-C30, psychological distress**
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## INTRODUCTION

RADIOTHERAPY is a potent palliative treatment modality, particularly in treatment of bone metastases [1], inoperable lung cancer [2], haemorrhage and obstruction [3], and a series of other conditions due to progressive malignant disease. The primary goal of palliative treatment is to reduce symptoms, to stabilise or improve patients' levels of functioning, to reduce hospitalisation and to improve patients' quality of life (QOL). The effect of such treatment traditionally has been evaluated in terms of symptom-free and overall survival. At best, in some trials, the palliative effect has been evaluated by the frequency or intensity of a given symptom measured by the physicians [4, 5]. More recently, however, efforts have been mounted to measure treatment effect by means of patients' self ratings of their health-related QOL.

Early on, the methods available to measure QOL were relatively limited, and the methodological literature was contradictory. The recommendations varied from the use of long, extensive questionnaires [6] to the use of only one or two questions [7]. During the last decade, a range of QOL measures have been developed and validated for use in clinical trials [8–11]. While the content, scoring, method, design and analysis of the measures have varied to some degree, they reflect a common definition and a common strategy for using QOL in clinical research [12–15]. Most QOL measures incorporate broad health-related quality of life dimensions: physical function (including both functional status and symptom experience), emotional functioning, and social functioning. Each of the QOL dimensions is assessed from the patient's point of view.

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Cancer (EORTC) Study Group on Quality of Life has developed a cancer specific QOL questionnaire (EORTC QLQ-C30) [16]. When employed in a cultural diverse sample of patients with lung cancer, the QLQ-C30 was found to be a reliable and valid measure of patients self-reported health-related QOL [16]. In the present study, the validity and reliability of the QLQ-C30 was tested in a population of patients treated with palliative radiotherapy.

## PATIENTS AND METHODS

*Study population and data collection*

During a 3-month period, patients treated with palliative radiotherapy in four hospitals in Norway were recruited into the study. All patients were included, with the exception of those who had a very poor performance status, and those who were unable to complete the questionnaire, either because of serious physical or psychological morbidity. The patients were asked to complete the questionnaire before the start of radiotherapy. If necessary, the patients were given brief instructions about how the questionnaire should be completed. 4 weeks after beginning radiotherapy, a second questionnaire was mailed to the patients at their home and was returned by mail to the study co-ordinator.

*EORTC Core Quality of Life Questionnaire (EORTC QLQ-C30)*

The EORTC QLQ-C30 is composed of 9 multi-item scales: 5 functioning scales (physical, role, cognitive, emotional and social), a global QOL scale, and 3 symptom scales (fatigue, pain and nausea/vomiting). In addition, several single item symptom measures are used.

The items comprising the physical functioning and role functioning scales employ "yes/no" response choices. The two items of the global quality of life scales use a modified 7 point linear analogue scale. All other items are scored on a 4 point categorical scale ranging from 1 "not at all" to 4 "very much". All scales and single items are linearly transformed to a 0–100 scale. For the five functioning scales and the global quality of life scale, a higher score represents a better level of functioning. For the symptom scales and items, a high score corresponds to a higher level of symptomatology.

*Psychological distress*

Psychological distress was measured by The General Health Questionnaire, 20 item version (GHQ-20) [17]. The GHQ-20 is a widely used scale for assessing subjective well-being and psychological distress. The questionnaire was originally designed as a screening instrument for psychiatric disorders in community settings. The 20 item version used in the present study is designed specifically for somatically ill patients [18]. Symptoms of a somatic nature are not included in the questionnaire.

*Pain scale*

Pain intensity was assessed with both a 5 point scale (ranging from "no pain" to "severe pain") and a 10 cm visual analogue scale. Pain frequency was measured with a 5 point scale ranging from "all day" to "not at all".

*Analysis plan*

A range of analyses were carried out to evaluate the hypothesised scale structure of the questionnaire (multi-trait scaling) and to estimate the scale reliability. The validity of the questionnaire was evaluated by examining: (1) the correlations among the QLQ-C30 scales; (2) the correlation between the QLQ-C30 subscales and other criteria measures (GHQ-20 and pain scale).

*Multitrait scaling*

A multitrait scaling analysis [19] was employed to test for item convergent and discriminative validity. This technique is based on the examination of item-scale correlations. Evidence of item convergent validity was defined as a correlation above 0.40 between one item and its own scale (corrected for overlap). Support for item discriminant validity was based on a comparison of the magnitude of the correlation of an item with its own scale as compared with other scales. A definite scaling error was defined as a correlation of an item with another scale that exceeded the correlation with its own scale by 2 standard errors. A probable scaling error was defined as a correlation between an item and another scale that exceeded the correlation with its own scale, but by less than 2 standard errors.

*Reliability*

The reliability of each scale (i.e. internal consistency) was assessed by Cronbach's alpha coefficient [20]. A value of 0.70 or greater was considered as acceptable for group comparison [21].

*Validity*

Construct validity was evaluated by examining the direction and magnitude of correlation among the various scales composing the QLQ-C30. It was hypothesised that scales that were conceptually related (e.g.) (physical functioning, role functioning) would correlate substantially with each other (Pearson's correlation $r \geq 0.40$). Too high a correlation between scales e.g. (above 0.70) was considered undesirable in that it would call into question the distinctiveness of the concepts being measured.

Additionally, the validity of the emotional function scale of the QLQ-C30 was examined by correlating it with the criterion measure, the GHQ-20. Similar analysis was undertaken for the QLQ-C30 with subscale, using alternative self-rating measures of pain as criterion variables. Finally, paired Student's *t*-tests were used to examine change of the QLQ scores between pretreatment and 4 week assessment points.

## RESULTS

*Patients' characteristics*

247 patients completed the first, pretreatment questionnaire. Of the 247 patients, 181 (73%) completed the second questionnaires 4 weeks after radiotherapy. 3 patients who did not answer the majority of the questions were excluded from the data analysis. Less than 5% of the patients required assistance in completing the questionnaires.

The mean age of the sample was 64 years (range 27–90 years). The majority of the patients had a primary diagnosis of lung cancer (32%), prostate cancer (13%) or breast cancer (23%). Other diagnosis included: myeloma (4%), gastrointestinal cancer (5%), and rectal cancer (4%). The majority of the radiotherapy fields were given against pain due to bone metastases, lung tumours and metastasis to the brain, chest wall and mediastinum. Other localisations of metastasis or primary tumour were soft tissue, muscles, lymph nodes and skin.

*Multitrait scaling*

The multitrait scaling analysis of the QLQ-C30 was performed for both pretreatment ($n = 247$) and follow-up ($n = 181$). At pretreatment, all items scale correlations were above 0.40. At follow-up, 4 correlations below 0.40 were observed.

*Table 1. Content and reliability of the EORTC Core Quality of Life Questionnaire (QLQ-C30)*

| Content area (scale) | No. of items | Before treatment reliability ($n$ = 247) (α-coeff.) | After treatment reliability ($n$ = 181) (α-coeff.) |
|---|---|---|---|
| Functioning scales | | | |
| Physical | 5 | 0.77 | 0.75 |
| Role | 2 | 0.68 | 0.67 |
| Cognitive | 2 | 0.62 | 0.69 |
| Emotional | 4 | 0.80 | 0.85 |
| Social | 2 | 0.78 | 0.82 |
| Global quality of life | 2 | 0.88 | 0.92 |
| Symptom scale/items | | | |
| Fatigue | 3 | 0.87 | 0.88 |
| Pain | 2 | 0.89 | 0.75 |
| Nausea and vomiting | 2 | 0.81 | 0.74 |
| Dyspnoea | 1 | — | — |
| Sleep disturbance | 1 | — | — |
| Appetite loss | 1 | — | — |
| Constipation | 1 | — | — |
| Diarrhoea | 1 | — | — |
| Financial impact | 1 | — | — |

187 tests of item discriminant validity were performed for the pretreatment and follow-up questionnaires, respectively. For the pretreatment questionnaire, one definitive and two probable scaling errors were noted in the role functioning scale and one probable scaling error in the physical functioning scale.

For the following questions, a total of five probable scaling errors were found: three in the role functioning scale, one in the cognitive functioning scale, and one in the nausea and vomiting scale. The very low number of scaling errors (2.1% before and 2.6% at follow-up) lend strong support to the hypothesised scale structure of the QLQ-C30.

*Scale reliability*

Scale reliability ranged from 0.62 to 0.89 before treatment and from 0.67 to 0.92 at follow-up (Table 1). Scale reliability was similar for younger versus older patients, and for those with low versus high education levels. The lowest reliability was obtained in the role and cognitive functioning scales.

*Validity*

*Inter-scale correlations.* Two correlation matrixes were constructed, including all 9 scales of the QLQ-C30 (Table 2) administered before and after treatment. As expected, the strongest correlations were found between the physical functioning, role functioning (0.72, 0.67), and fatigue (−0.60, −0.63) scales.

The emotional functioning scale did not correlate above 0.50 with any other scales except with cognitive functioning (0.55 after treatment). Global Quality of Life correlated strongly (0.50–0.65) with physical functioning, role functioning, social functioning and fatigue, and less with cognitive functioning and emotional functioning.

The emotional functioning scale correlated highly with GHQ-20 both pre- and post-treatment (−0.62 and −0.71). At both pre- and post-treatment, the EORTC pain scale correlated highly with items assessing pain intensity (0.85, 0.78), pain frequency (−0.69, −0.66) and pain intensity measured on a visual analogue scale (VAS scale) (0.79, 0.71).

*Responsiveness to change in health status over time*

For the total sample, patients' scores on the physical and role functioning scales declined from 58 to 54, and from 55 to 48 from pre- to post-treatment ($P<0.05$), respectively. Patients reported significantly ($P<0.05$) more fatigue (mean: 48 versus 57), emesis (mean: 15 versus 20), appetite loss (mean: 30 versus 38) and diarrhoea (mean: 10 versus 15). No reduction in pain or dyspnoea was observed for the total sample. Patients who reported "quite a bit" or "very much" pain ($n$ = 86) or dyspnoea ($n$ = 56) were analysed as separate groups. The pain subsample reported a significant reduction in pain from pre- to post-treatment (mean: 77 versus 63, $P<0.001$). In the dyspnoea subgroup, a statistically significant reduction was observed in self-reported dyspnoea (mean: 76 versus 64, $P<0.001$).

## DISCUSSION

The multitrait scaling analysis confirmed the hypothesised structure of the questionnaire. The weakest scale was the role functioning scale. Similar results were found in the EORTC field study in patients with advanced lung cancer, and in a study on head and neck cancer patients [16, 22]. Future versions of the questionnaire will, therefore, test alternative items for assessing role functioning. The fifth item in the physical functioning scale seems to be somewhat problematic. It is also important to note that the nausea and vomiting scale and the cognitive functioning scale showed low (<0.40) item scale correlations after treatment. These two questions comprise only two items, and the low correlations are probably due to skewed answer distributions in one of the items within the scales. These scales should be assessed carefully in future studies.

*Table 2. EORTC QLQ-C30: correlations among scales before and after treatment**

| | | PF | RF | CF | EF | SF | QOL | F | P | NV |
|---|---|---|---|---|---|---|---|---|---|---|
| Physical functioning | (PF) | | 0.67 | 0.39 | 0.22 | 0.49 | 0.62 | −0.63 | −0.52 | 0.15 |
| Role functioning | (RF) | 0.72 | | 0.36 | 0.34 | 0.57 | 0.55 | −0.55 | −0.46 | −0.22 |
| Cognitive functioning | (CF) | 0.37 | 0.28 | | 0.55 | 0.41 | 0.48 | −0.57 | −0.46 | −0.31 |
| Emotional functioning | (EF) | 0.20 | 0.18 | 0.42 | | 0.44 | 0.45 | −0.47 | −0.46 | −0.35 |
| Social functioning | (SF) | 0.50 | 0.51 | 0.42 | 0.34 | | 0.50 | −0.58 | −0.44 | −0.19 |
| Global QOL | (QOL) | 0.64 | 0.57 | 0.40 | 0.39 | 0.58 | | −0.74 | −0.45 | −0.31 |
| Fatigue | (F) | −0.60 | −0.54 | −0.36 | −0.36 | −0.52 | −0.70 | | 0.52 | 0.39 |
| Pain | (P) | −0.56 | −0.47 | −0.43 | −0.56 | −0.54 | −0.56 | −0.54 | | 0.30 |
| Nausea/vomiting | (E) | −0.30 | −0.26 | −0.30 | −0.25 | −0.23 | −0.39 | −0.46 | −0.34 | |

*Before treatment under the diagonal; after treatment above the diagonal. QOL, quality of life.

The reliability of the role functioning and cognitive function scales was somewhat minor compared to the remaining scales (reliability of 0.62–0.69). At the second point in time, the reliability was somewhat improved. This may be explained by the selection of patients at the second point in time as compared with patient selection at the baseline evaluation. Patients with the most advanced disease had a high probability of dying before the second evaluation. The reliability of the different subscales were similar or better than the corresponding results from the EORTC study on lung cancer patients [16].

The criterion validity of the emotional function scale was confirmed by high correlation with GHQ-20. The criterion validity of the pain scale was promising, with high correlation with single items measuring "pain last week", pain frequency and pain on a VAS scale.

Clinical data would have strengthened the validation procedure. However, neither tumour response nor patient weight loss/gain seem to be valid clinical anchor points in this patient population. Tumour response is of minor, if any, clinical importance in this population. Doctors' or nurses' ratings of physical performance, or other QOL dimensions might have shed more light on the validation procedure. However, these data were not collected.

The EORTC QLQ-C30 exhibited satisfactory to excellent psychometric properties, and it was found to be useful for detecting changes over time. The high degree of compliance in the present study indicates that the format and the content of the questionnaire were acceptable for patients with advanced malignant disease.

During recent years, several other cancer-specific QOL instruments have been developed and their psychometric properties have been established. Instruments, such as the Function of Living Index Cancer (FLIC) [9], the Cancer Rehabilitation Evaluation System (CARES) [10], and the Rotterdam Symptom Check List (RSCL) [11], have been found to be valuable for assessment of QOL in clinical trials. It is unlikely that any of these measures could be ranked as "the gold standard". The EORTC QLQ-C30 is the only cancer-specific questionnaire which has been crossnationally and crossculturally developed. A similar approach is also used in developing EORTC disease-specific modules. This approach strengthens the validity of the questionnaire planned for use in multinational studies.

Several hundred QOL instruments have been used in the field of health-related QOL assessment [23]. Many of these are designed to measure QOL across diseases. It is unclear whether disease-specific questionnaires or generic questionnaires are most informative. In this study, however, it is indicated that disease-specific symptoms are most sensitive to detect changes over time, after palliative radiotherapy. No changes were found in patients in terms of emotional and cognitive functioning before and after treatment.

The EORTC QLQ-C30 was designed to measure QOL in cancer clinical trials in general, not particularly in cancer patients with advanced disease. The present study shows that the questionnaire is also suitable to measure QOL in patients with advanced disease receiving palliative radiotherapy.


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