

Reliability and validity of the EORTC QLQ-C30 in palliative care cancer patients

Research Article

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Abstract: Palliative care aims at improving the patient's quality of life. The assessment of this quality of life (QoL) is crucial for the evaluation of palliative care outcome. Many patients require hospital admissions for symptom control during their cancer journey and most of them die in hospitals, although they would like to stay at home until the end of their lives. In 1986, the European Organization for Research and Treatment (EORTC) initiated a research programme to develop an integrated, modular approach for evaluating the quality of life of patients participating in international clinical trials. This questionnaire measures cancer patients' physical, psychological and social functions and was used in a wide range of clinical cancer trials with large numbers of research groups and also in various other non-trial studies. The aim of this study was to evaluate the psychometric properties, especially the reliability, validity and applicability of the EORTC QLQ-C30 in a German sample of terminally ill cancer patients receiving palliative care in different settings. The questionnaire was well accepted in the present patient population. Scale reliability was good (pre-treatment 0.80) especially for the functional scale. The results support the reliability and validity of the QLQ-C30 (version 3.0) as a measure of the health-related quality of life in German cancer patients receiving palliative care treatment.

Keywords: EORTC QLQ C30 • Health-related quality of life • Palliative care • Cancer • Nursing research

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1. Introduction

Palliative care is defined by the World Health Organization as an approach that improves the quality of life of patients and their families, whom face problems associated with life-threatening illness, through the prevention and relief of suffering by means of early identification, impeccable assessment and treatment of pain and other physical, psychosocial and spiritual problems. Palliative care:

- provides relief from pain and other distressing symptoms;
- affirms life and regards dying as a normal process;

- intends neither to hasten nor postpone death;
- integrates the psychological and spiritual aspects of patient care;
- offers a support system to help patients live as actively as possible until death;
- offers a support system to help the family cope during the patients illness and in their own bereavement;
- uses a team approach to address the needs of patients and their families, including bereavement counselling, if indicated;
- will enhance quality of life, and may also positively influence the course of illness;

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- is applicable early in the course of illness, in conjunction with other therapies that are intended to prolong life, such as chemotherapy or radiation therapy, and includes those investigations needed to better understand and manage distressing clinical complications.

Therefore, there is a wide scope for research. In addition, there is also a need for research into the management and organisation of services and their quality of care. In recent years, attention on palliative care has a considerable increase in most European Countries in all areas of health care. As palliative care emerges it is becoming clear that it needs to take place in a wide range of settings, e.g., hospital, hospice, nursing home, day care and patients' homes. In Germany the progression in this specialty is far behind the advancements, *i.e.*, the UK. Currently, there is a reorganisation in the German health care system. There is the official political principle that home care is primary to hospital or nursing home care, thus, in the next few years, there will be a reduction in hospital beds by one-third, which will enforce a rapid change from hospital to home care. German politicians have yet to find a solution to transfer the high quality of palliative care from the established settings, *i.e.*, hospice or palliative care units to the community environment. The new situation and the demand for more specialised palliative care teams increase the need for evaluation of the effect and quality of care.

Health-related quality of life assessment in cancer patients has attracted an increasing interest in recent years, particularly in the oncology nursing discipline. There it includes an assessment of the impact of the disease and its treatment on the physical, psychological and social functioning of the patient [2]. Many excellent validated self-completion questionnaires to measure HRQOL for patients with cancer are available, e.g., EORTC QLQ-C30, Functional Assessment of Cancer Therapy (FACT) (Holzner, Kemmler *et al.* 2004) [30], Rotterdam Symptom Checklist (RSCL) (Hardy, Edmonds *et al.* 1999) [28] and Functional Living Index-Cancer (FLIC) (Annunziata, Foladore *et al.* 1998; Kuenstner, Langelotz *et al.* 2002) [5,40]. Other relevant instruments for palliative care include the Support Team Assessment Scale (STAS) (Carson, Fitch *et al.* 2000) [16], the McMaster Quality of Life Scale (MQLS) (Sterkenburg, King *et al.* 1996) [52] and the Symptom Distress Scale (SDS) (Heedman and Strang 2001) [29]. All those questionnaires are multidimensional, covering a minimum of the physical, psychological and social domains as well as some overall judgements of the validation of life or the health condition. It is hardly necessary (or advisable) to develop more or new instruments, but there should be clear recommendations

and guidelines on which instruments are capturing the most relevant issues of concern for people with palliative care needs although there has been much criticism of the EORTC QLQ-C30 for use in palliative care by not covering important domains (e.g. spirituality).

In 1986, the European Organization for Research and Treatment of Cancer (EORTC) study group on quality of life initiated a research programme the long-term objective of which was to develop an integrated measure system for evaluating the HRQOL of patients participating in international clinical trials (Aaronson, Ahmedzai *et al.* 1993) [1].

Systematic evaluation of health-related quality of life (HRQoL) could enable clinicians to identify patients who are at an increased risk of encountering psychosocial problems, so that appropriate intervention strategies can be initiated where necessary (Bliss and While 2003) [13]. Sufficient validity and reliability are mandatory for any measuring tools (Kaasa, Bjordal *et al.* 1995; Klee, Groenvold *et al.* 1997; Sprangers, Cull *et al.* 1998) [33,37,50] especially for the use in palliative care with terminally ill patients.

The EORTC quality of life questionnaire is an integral system for assessing the HRQoL of cancer patients. A first-generation core questionnaire, the EORTC QLQ C36, was developed in 1987 by Aaronson and Beckmann (Beckmann, Betsholtz *et al.* 1988) [10]. The EORTC QLQ-C30 is a second-generation questionnaire. It is a 30-item questionnaire with a 4-point answer scale. Following its general release in 1993 (Aaronson, Ahmedzai *et al.* 1993) [1], the QLQ-C30 was used in a wide range of clinical cancer trials by a large number of research groups (Anderson, Aaronson *et al.* 1996; De Boer, Sprangers *et al.* 1996; Curran, Fossa *et al.* 1997; Curran, van Dongen *et al.* 1998; Kiebert, Curran *et al.* 1998; Langendijk, Aaronson *et al.* 2000; de Haes, Curran *et al.* 2003) [1,4,20,21,23,35,42,50] and was additionally used in various other non-trial studies (Ahmedzai and Brooks 1997; Stromgren, Groenvold *et al.* 2001; Bestall, Ahmed *et al.* 2004) [2,11,54]. The EORTC QLQ-C30 has been designed for use in a range of languages and cultures, the validation of the QLQ-C30 specific to a German population and the development of disease-specific modules to supplement the EORTC QLQ-C30. Patients receiving palliative care treatment are usually in an end-stage situation on their illness, in this study cancer. At present, they have received curative treatments, which include chemotherapy, hormonotherapy, radiotherapy and surgery. But when the cancer deteriorates under these therapies and no other possibilities did help, the palliative care treatment increasingly became the centre of clinical possibilities.

Palliative care comes from the Latin word *palliare*, which means to put a coat at some one's body. At present, symptom control is standing in the centre of attention and not the healing of the cancer. Palliative care emerges as an important field in health care; it takes place in a wide range of settings, e.g., hospital, hospice, nursing home and patient's home. People being terminally ill have a specific set of circumstances. Active therapy being received is not being offered with curative intent. Physical deterioration has come to affect everyday functioning, and deterioration has become progressive and irreversible. Survival is likely to be counted in weeks and months rather than years. These problems are those that face health care practitioners, which are responsible for setting standards, developing valid and reliable methods of assessing that standard and being able to use these findings for informing policymakers and healthcare authorities. However, little information is available regarding the psychometric properties of the EORTC QLQ-C30 in such a terminally ill cancer patient population, when used in different care settings (Kaasa, Bjordal *et al.* 1995; Klee, Groenvold *et al.* 1997; Sprangers, Cull *et al.* 1998)[33,37,50].

Therefore, this study is developed to evaluate the psychometric properties and to look at the appropriateness, relevance, feasibility and responsiveness to change of the EORTC QLQ-C30 in terminally ill patients receiving palliative care in hospital care and in home care.

2. Material and Methods

A descriptive study design is utilised to assess the practicality, reliability and validity of the EORTC QLQ-C30 (version 3.0) questionnaire with regard to a German sample of terminally ill cancer patients receiving palliative care either in hospital or at home.

Patients of a general hospital and ten specialised palliative home care services completed a questionnaire for the study upon admission to the service and again after a week of palliative symptom control.

2.1. Patients

The study was performed at a cancer care unit of a German general hospital and in 10 specialised palliative home care services in South Germany. The 1000-bed hospital has a palliative care unit on an oncology ward. The specialised palliative home care services are hospital-based, which means that they are allocated in the hospitals, they are part of them, they get paid by them but they spend most of their time outside the hospital, in the homes of the patients. This kind of service is very exclusive traditionally these are two different sectors in

the German health care system. Most of these services have been operating for about 15 years. The home care teams are specially trained nurses who are visiting the patients and their families at their homes and take over responsibility together with the general practitioners. With the support from the home care teams, patients who all suffer from end-stage cancer, are able to stay at home and do not have to be admitted to a hospital for symptom control. Patients are treated for pain relief and management of other cancer-related symptoms like dyspnoea, fatigue, constipation, diarrhoea, nausea, vomiting and anorexia. A stratified random sample (Polit and Sherman 1990)[48] of 121 patients was extracted from a total of 250 cancer patients, who were treated in the hospital or home care services. Every second patient was selected on basis of the performance status, if the inclusion criteria were fulfilled. Inclusion criteria were: older than 18 years, no cerebral metastases, no known psychiatric disorder, a Karnofsky performance status (Karnofsky 1968; Schaafsma and Osoba 1994) [34,49] of not less than 40%, cognitive capability to fill in the questionnaire and a good command of the German language. All participating patients were no longer under anticancer treatment. Prior to completing the questionnaire all patients who agreed to participate, signed an informed consent after they and their next of kin had received detailed information. The study was approved by the local medical ethics committee.

2.2. Instrument

Demographic and clinical data were recorded by the study investigators or the staff on a separate sheet. The health-related quality of life was measured with the EORTC QLQ-C30. The EORTC QLQ-C30 was designed to cover several aspects of the patient's health-related quality of life (physical as well as psychosocial aspects). The 30-item EORTC QLQ-C30 deals with the health and well-being in the past week. Each item can be scored on a 4-point scale: not a problem; a little; quite a bit; and, very much. The responses regarding the items are converted to a 0–100 scale. The 30 items are divided into 6 functional scales: physical function (5 questions); social function (2 questions); role function (2 questions); emotional function (4 questions); cognitive function (2 questions); global health status/QoL (2 questions) and 3 scales comprising fatigue (3 questions); pain (2 questions); nausea and vomiting scales (2 questions) and 6 items about symptoms (lack of appetite, constipation, diarrhoea, dyspnoea, insomnia and financial difficulties). Scores on items of each scale are summated to one total score. A high score on each scale represents a high level in the examined topic, a high score on the global health status/

Table 1. Content of the QLQ-C30 dimensions scales and single item scales.

Content	QoL dimension	No. of questions	Literal interpretation of the lowest and highest scores: In the past week I was.....	
			Lowest possible = 0 Questions	Highest possible = 100
Global	Global QoL	2	Overall physical condition and Quality of life was very poor	Overall physical condition and Quality of life was excellent
Functional	Physical Function	5	Was confined to bed, needed help with dressing, washing and eating	Was able to do strenuous physical activities
	Role Function	2	Was completely unable to work at a job or do household jobs	Was not limited at all in doing either work or household jobs
	Emotional Function	4	Felt very tense, irritable and depressed and worried a lot	Did not feel at all tense, irritable or depressed and did not worry at all
	Social Function	2	Physical condition and medical treatment interfered very much with family life and social activities	Physical condition and medical treatment did not interfere at all with family life and social activities
	Cognitive Function	2	Had a lot of difficulty with concentrating and remembering things	Did not have any difficulty with concentrating or remembering things
Symptoms	Nausea and Vomiting	2	Did not feel at all nauseous and did not vomit	Felt very nauseous and vomited frequently
	Pain	2	Did not have any pain, and pain did not interfere at all with daily activities	Had a lot of pain which interfered strongly with daily activities
	Fatigue	3	Did not feel at all weak or tired and did not need to rest at all	Felt very weak and tired and needed to rest a lot
Single items	Constipation	1	Have you been constipated?	Felt very constipated
	Diarrhoea	1	Have you had diarrhoea ?	Have diarrhoea many time a day
	Sleep	1	Have you had trouble sleeping?	Have a lot sleeping problems
	Dyspnoea	1	Were you short of breath	I am breathless most of the time
	Appetite	1	Have you lacked appetite ?	Have appetite loss most of the time
	Financial	1	Has your physical condition caused you financial difficulties?	Have a lot of financial problems

QoL for instance represents a high QoL and a high score in a symptom scale/item represents a high level of symptomatology/problems. (Table 1)

The staff of the palliative care unit, the home care teams and the study investigator additionally recorded data according to the applicability and practicality of the quality of life instrument. They asked patients how long it took them to answer all questions, and about any inconvenience and burden. Finally, the investigators expressed their opinion on how much pressure those questions put on the patients. An additional questionnaire with open-ended questions was used to obtain information about the appropriateness and feasibility of the instrument.

2.3. Procedure

Patients were asked to complete the first questionnaire within the first 24 hours upon admission to the unit or home care services. All patients were given brief

instructions on how to complete the questionnaire. The staff of the palliative care unit, the home care teams and the study investigator were available for questions regarding the study and the completion of the forms.

2.4. Data analysis

All statistical procedures were performed in accordance with the instructions contained in the EORTC QLQ-C30 scoring manual (Arraras, Arias *et al.* 2002; Fayers and Bottomley 2002)[6,26].

Average values of descriptive methods, standard deviations for the continuous variables and frequencies and percentages for the categorical variables were used to describe the data. For the examination of the construct validity of the QLQ-C30 principal components analysis was carried out, To evaluate the internal consistency of the EORTC QLQ-C30 the Cronbach's alpha coefficients were calculated (Table 4). Using Pearson's coefficient of correlation between the QLQ-C30 dimensions as a

Table 2. Patients' sociodemographic and medical characteristics.

	Total sample (n=121)	Home Care (n=64)	Hospital Care (n=57)
Gender			
Females	70 (57.8%)	35 (61.4%)	35 (54.7%)
Males	51 (42.2%)	22 (38.6%)	29 (35.3%)
Age (years)	35-94	38.5-84.4	35-94
Age (mean)	63.1	61.7	64.4
Karnofsky Index (Mean)	48.5	50.7	46.6
Living situation			
Alone	39	15	24
With spouse or partner	76	45	31
With others	6	4	2
Cancer origin			
Gastrointestine	38	19	19
Lung	21	8	13
Breast	21	14	7
Male genitals and female genitals	23	12	11
Others	18	11	7

Table 3. Descriptive statistics.

	Items (1)	Mean score	S.D.
Physical function	1,2,3,4,5	30.86	24.41
New role function	6,7	21.69	22.81
Emotional function	21-24	41.34	23.23
Cognitive function	20,25	58.56	30.34
Social function	26,27	38.47	29.88
New global health/Quality of life	29,30	31.56	19.07
Fatigue	10,12,18	72.50	21.19
Nausea and vomiting	14,15	46.30	33.65
Pain	9,19	60.72	31.93
Dyspnoea	8	61.49	35.29
Sleep disturbance	11	55.65	32.99
Lack of appetite	13	64.79	30.00
Constipation	16	36.61	36.17
Diarrhoea	17	16.78	31.08
Financial Impact	28	32.99	33.52
Karnofsky		48.50	13.10

1. Numbers correspond to the item numbers in the questionnaire

2. scores range from 0-100 with a high score representing a higher level of functioning

3. scores range from 0-100 with a high score representing a greater degree of symptoms

patient perspective and the Karnofsky index as an expert perspective construct validity was calculated (Table 5). There was no need to omit any cases from the analysis due to missing data because all questionnaires from the selected patients have been fully answered. The statistical software SPSS PC for Windows (version 11) was used in the statistical analysis.

3. Results

3.1. Demographic characteristics

The patient sample consisted of 64 patients in the hospital group and 57 in the home care group, with in total 51 males (42.2%) and 70 females (57.8%). Within the hospital sample, there were 29 males (35.3%) and 35 females (54.7%), and within the home care sample, there were 22 male (38.6%) and 35 female (61.4%). The mean age was of 63.1 years (range 35–94 years) in the total sample. The mean age of the hospital group is 64.4 years and of the home care group it was 61.7 years. The mean Karnofsky Index of the total group was 48.5 (range 40-90, mean of 46.6 in the hospital group and 50.7 in the home care setting). The most prevalent diagnoses were gastro-intestinal cancer (31%), urogenital cancer (19.3%), lung cancer (17.4%), breast cancer (17.4%) and other cancer sites (15.1%) (See Table 2). The majority of the total sample (n=76) lived together with their partners and 39 patients lived on their own at the time of assessment.

3.2. Description of the scales

In the functional scales cognition was rated highest with a mean value of 58.6, the new role function lowest with a mean value of 21.7 and in the symptom scales fatigue was rated highest with a mean value of 72.5, lack of appetite with 64.8 followed by dyspnoea with 61.5 and pain with 60.7 (See Table 3).

Table 4. Reliability Cronbach's alpha

	Number	Cronbach's alpha
Functional scale	5	0.80
Symptoms scale	3	0.63
Single symptoms	6	0.10

3.3. Applicability and practicality

The mean time required to complete the QLQ-C30 (version 3.0) was 9 minutes (range 7-15 minutes). No patient reported any difficulty or confusion regarding the questionnaire items. All 250 patients have been able to answer the questionnaire by themselves without excessive use in time and strength for completion.

3.4. Psychometric testing of the instrument

3.4.1. Cronbach's α

Cronbach's α was calculated for the a-priori considered dimensions of the QLQ-C30 to explore reliability. The reliability coefficients (Cronbach's Alpha) for the functional scales was 0.80 and for the symptom scales 0.63. Cronbach's alpha for the single symptom items was very low (Table 4).

3.4.2. Pearson Correlation

Although the correlation between the Karnofsky Index and the dimensions of the QLQ-C30 were significant, only the functional scale (0.44) and the global item (0.54) showed a medium association, whilst there was only little to none association regarding the symptom scale (0.18), which reveals that only parts of the patients' view on LQ were covered by an external view. The strongest correlation upon was observed between physical functions and symptoms. Substantial correlation (>0.40) was also noted between the physical functions scale, emotional functions, social functions and the quality of life item. Conversely, a relatively weak correlation was observed between the nausea/vomiting scale and the functional scales. In general, the inter-scale correlation

was of a moderate degree only, indicating that although related they were assessing distinct components of the quality of life instrument.

4. Discussion

An increasing number of clinicians use the QLQ-C30 for assessing and monitoring patients in routine clinical practice. The study showed that the questionnaire was well accepted in the present patient population. Well to the point that even the elderly patients and those with terminal illness have little problems in evaluating their HRQOL. In a recent published study in patients with advanced cancer and a median life expectancy of 2 months, it was shown that patients completed QOL measures such as the EORTC QLQ C-30 until the last 1-2 weeks of life (Stromgren and Groenvold, 2002) [53]. Scale reliability was sufficient, especially for the functional scale and the symptom scales, not so for the single symptom scales. High validity was also found in the statistical approaches used. The availability of the questionnaire in a large number of languages opens new ways for comparing samples all around the globe and also enhances the effectiveness of different palliative care services (Kobayashi, Takeda *et al.* 1998; Mercier, Bonnetterre *et al.* 1998; Zhao and Kanda 2000; Kyriaki, Eleni *et al.* 2001; Klepstad, Loge *et al.* 2002; Chie, Chang *et al.* 2003; Conroy, Mercier *et al.* 2004; Morita, Shimozuma *et al.* 2004; Yun, Park *et al.* 2004) [17,19,38,39,41,43,44,58,59]. As stated in the WHO definition of palliative care, its goal is the achievement of the best possible QOL for patients and their families. The use of QOL as an outcome is therefore self-explanatory.

Many patients of the sample reported positive experience because they were given the opportunity to talk about their health and illness experiences. The weakest scale from a psychometric perspective is

Table 5. Correlation matrix (Pearson) $n = 121$.

		Karnofsky Index	New global health/ Quality of life	Symptomsscale	Functional scale
Karnofsky Index		1			
	N	121			
New global health/Quality of life		.54(**)	1		
	N	121	121		
Symptoms scale		-.18(*)	-.32(**)	1	
	N	121	121	121	
Functional scale		.44(**)	.56(**)	-.52(**)	1
	N	121	121	121	121

** The correlation on the niveau of 0,01 is significant.

* The correlation on the niveau of 0,05 is significant.

the financial impact scale and it should be discussed whether it is still necessary for the study population. Some of the items are less relevant in their situation. For example, the question about trouble doing strenuous activities is largely irrelevant to these patients. It could also be suggested, for example, that when assessing these patients the emotional function (EF) scale can be shortened from the original four items to three of only two. The tests of validity yielded generally consistent results. In addition to previously conducted validation studies (Aaronson *et al.* 1993)[1] of EORTC QLQ C-30 the sample was not restricted to one specific type of cancer but included a wide variety of diagnoses in different palliative care settings. The measurement showed the requirement to also introduce the patients' view when evaluating LQ apart from the already existing measurement of the Karnofsky Index, which is rated by the professionals (Schaafsma and Osoba 1994) [49]. This was indicated in a number of studies that recorded low levels of reliability in the professionals' performance status ratings and low levels of agreement between ratings provided by professionals and those provided by their patients (Schaafsma and Osoba 1994; Stromgren, Groenvold *et al.* 2002)[49,53]. Therefore, functionally oriented aspects of HRQOL could anticipate even greater problems when assessing subjective experiences, e.g. pain and fatigue (Campbell and Hatley 2000; Steer, Marx *et al.* 2001; Stromgren, Groenvold *et al.* 2002; Bostrom, Hinic *et al.* 2003)[14,15,51,53]. However, there is also an increasing recognition of the need to more systematically assess the impact of cancer and its treatment on the functional, psychological and social health of the patient (Balmer, Thomas *et al.* 2001; Newbury 2002; Douglas, Halliday *et al.* 2003; Hughes, Aspinall *et al.* 2003)[8,24,31,46].

5. Conclusions

The EORTC QLQ-C30 has been used in palliative care research and is one of the most widely used instruments for assessing physical and psychosocial symptoms and functionality of patients with cancer, in both curative and palliative settings. The major strengths of the German version of the EORTC QLQ-C30 (version 3.0) are that its formerly satisfactory psychometric properties were found to be valid and reliable. The study yielded results that generally satisfied the conventional psychometric criteria before palliative care treatment. No cases had to be omitted from the analysis due to missing data and there was a high degree of compliance, which indicates that the format and the content of the questionnaire were acceptable for patients with an advanced malignant disease in need for palliative care, both in hospital and in home care settings. On the other hand, possible limitations could be the relatively small sample and a "good" performance status and the criticism, that the QLQ-C30 did not cover all important domains of terminally ill cancer patients, specifically spiritual. The results presume that the QLQ-C30 reliably and validly measures the HRQOL of German cancer patients under palliative care. We consider this version effective in the German palliative care settings as an outcome measurement and for assessing the HRQOL of advanced-stage cancer patients in international clinical trials. Studies with more study periods and larger sample sizes are needed to confirm our results and to allow their generalisation. Further results of the study will be published in additional papers, as part of a doctoral programme in nursing science.

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