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This is the author version of article published as:

Janda, Monika and Newman, Beth and Obermair, Andreas and Woelfl, Hedwig and Trimmel, Michael and Schroeckmayr, Heidi and Widder, Joachim and Poetter, Richard (2004) Impaired Quality of Life in Patients Commencing Radiotherapy for Cancer. *Strahlentherapie und Onkologie* 180(2):pp. 78-83.

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Impaired quality of life in patients commencing radiotherapy

for cancer

Prevalenz von reduzierter Lebensqualität am Beginn der

Strahlentherapie

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Short running title: Impaired quality of life in radiotherapy patients

Abstract

This study tested a three-item questionnaire of global quality of life (QOL) and pain in patients commencing radiotherapy, based on items from the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 instrument. In pre-test, the EORTC QLQ-C30 and the three-item short questionnaire were administered to 100 patients, yielding similar global QOL and pain scores. After the pre-test, the three-item questionnaire was administered to 1,837 patients prior to first radiotherapy treatment.

We identified 254 (13.8%) patients with impaired QOL. These patients had a mean global QOL score of 32.6 compared to 72.4 ($p < 0.001$) found in patients with satisfactory QOL. Patients with impaired QOL were also more likely younger than 60 years and treated for lung, gastrointestinal or head & neck cancer or advanced, metastatic cancer.

This brief instrument addresses important aspects of quality of life, is feasible to use in a clinical setting and therefore represents a potentially useful tool for detecting those patients who may benefit from further evaluation and/or psychosocial support.

Key Words: cancer, radiotherapy, quality of life, screening, psychosocial support.

Zusammenfassung:

Im Rahmen dieser Studie wurde ein Kurzfragebogen zur Erfassung der Lebensqualität basierend auf dem Lebensqualitätfragebogen der European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 entwickelt. In einer Pilotstudie wurden 100 Patienten randomisiert der EORTC-QLQ C30 und der 3-Fragen Kurzfragebogen vor Beginn der Bestrahlung vorgegeben. Beide Fragebögen erbrachten einander entsprechende Werte für die allgemeine Lebensqualität und das derzeitige Schmerzniveau der Patienten (Tabelle 1). Im Anschluß an diese Pilotstudie wurde der Kurzfragebogen 1837 Patienten vorgegeben. Patientencharakteristika finden sich in Tabelle 2 und 3.

Wir erfaßten 254 (13,8%) der Patienten welche unter einer beeinträchtigten Lebensqualität bereits vor Beginn der Bestrahlung litten. Diese Patienten hatten einen mittleren globalen Lebensqualitätswert von 32,6 im Vergleich zu 72,4 ($p < 0.001$), welcher bei Patienten mit zufriedenstellender Lebensqualität gemessen wurde. Patienten mit niedriger Lebensqualität waren jünger als 60 Jahre, und erhielten überdurchschnittlich häufig eine Behandlung wegen eines Bronchialkarzinoms, colorektalen Karzinoms, Kopf-Hals Tumors oder palliative Behandlung (Tabelle 2). Die Lebensqualitätswerte, die in der vorliegenden Stichprobe gemessen wurden, wurden weiterhin mit Normen, welche für die deutsche Bevölkerung für den EORTC-QLQ C30 vorliegen, verglichen (Abbildung 1a und 1b).

Der kurze Lebensqualitätsfragebogen, der hier präsentiert wurde, misst wichtige Aspekte der Lebensqualität, ist anwendbar auch in der arbeitsreichen Atmosphäre einer Tagesklinik, und könnte sich daher als wichtiges Screening-Instrument der Lebensqualität für die Strahlentherapie erweisen. Patienten mit schlechter

Lebensqualität am Beginn der Bestrahlung könnten in besonderem Ausmaß von zusätzlicher Betreuung und/oder Information profitieren.

Key Words: Krebs, Strahlentherapie, Lebensqualität, Screening, Psychosoziale Unterstützung.

Introduction

Diagnoses and treatments of cancer frequently impose significant burdens on patients. Quality of life (QOL) is affected by the diagnosis itself [22] as well as the diagnostic procedures, and often deteriorates further due to treatment-related side effects [7,14]. Patients suffer from reduced QOL and psychosocial problems even long after their cancer treatment has been completed [17]. QOL and psychological well-being are related to each other [18,27] and might predict the response to chemotherapy [16,31]. Early treatment of reduced quality of life and psychosocial distress could be beneficial for some but probably not all patients [30,31]. In a recent meta-analysis, psychological interventions appeared to be more effective if patients were selected for therapy rather than if they were just included on the basis of their cancer diagnosis [26]. Early psychological treatment might be especially important for patients undergoing radiotherapy [33], because patients are distressed before commencement of radiotherapy [13] and throughout treatment [24] and early intervention is effective in reducing patient distress [20]. However, no “gold standard” currently exists to identify patients who might benefit most from psychosocial or psychoeducational interventions.

Previous reports indicate that QOL measures might carry independent prognostic information [2,3,6,28], but others could not confirm these results and found only pain to be predictive for the outcome of lung cancer patients [10]. Baseline scores from the European Organisation for Research and Treatment Quality of Life Questionnaire (EORTC QLQ-C30) and two single questions (overall physical condition, overall quality of life) provided independent prognostic information in a series of patients with advanced stages at various tumor sites [3]. Single-item scales like the Spitzer Uniscale were compared with other QOL tools and were shown to be equally sensitive and

prognostically relevant as the more time-consuming methods [28]. The EORTC QLQ-C30 is easy to complete, however, in a hurried ambulatory setting might conflict with standard procedures.

Recently, German, population-based, reference data became available for the EORTC QLQ-C30 [23] and showed that the general population has a far from perfect QOL [5]. Fayers suggested using the population based reference data as a comparison for patient's scores by taking the absolute difference between the two values or computing a percentage reduction and to aim for QOL comparable to the general population in cancer patients as a minimal goal [5].

In order to identify patients with impaired QOL in a clinical setting, we designed a three-item screening questionnaire based on items from the EORTC QLQ-C30 instrument. In a pretest, patient responses to the three-item questionnaire were compared to the 30-item EORTC QLQ- C30 to establish comparability. It was then the aim of this study to test the feasibility of using the three-item questionnaire in an unselected group of patients commencing radiotherapy and to compare our results to those available in the literature [11,16,18,23,32].

Patients and Methods

Patients

All patients who were referred between August 1998 and November 1999 to the new patient clinic of the Radiotherapy Department of the University Hospital, Medical School of Vienna, were considered for this trial. Eligible patients had to meet the following criteria: histologically proven malignancy, age older than 18 years, first contact with our department, prior to receiving first radiotherapy treatment, not requiring constant hospital care, and able to understand German well enough to answer the questions. Patients were consented if they were able and willing to fill in the questionnaire. Due to organisational reasons we could not perform our study during some periods while administrative staff were on leave. Therefore only 2,026 of the 3,581 new patients could be screened for eligibility. Twenty-one (1.0%) patients younger than 18 years of age and 168 (8.3%) patients who refused to participate or did not meet the eligibility criteria were excluded from the study. Therefore 1,837 patients remained eligible for analysis.

Based on the diagnosis, each patient was managed by a team of specialized radiotherapists. Group one consisted of patients with breast cancer (breast), group two comprised women with gynaecological cancer and patients with urogenital cancer (GU/GYN). Group three included patients with cancer of the lung, the gastrointestinal tract, or head and neck cancer (Lung/GI/H&N). Group four comprised patients with lymphoma, leukemia (HAEM) or brain tumors. Patients were referred to group five mainly for the treatment of bone or skin metastases (Advanced Cancer).

Questionnaire

Two items addressing overall physical condition (OPC) and overall quality of life (OQOL) were taken with permission from the original EORTC QLQ-C30 [21]. OPC and OQOL are rated on a seven-point scale ranging from 1 (very poor QPC/OQOL) to 7 (excellent OPC/OQOL). To allow comparison with normative data, a score for global quality of life was computed by combining OQOL and OPC and linearly transforming the resulting summary score to a 0 to 100 scale with higher scores representing better global QOL [21]. The third item addressed pain during the last week. Item 9 from the original EORTC QLQ-C30 was recoded with permission from the EORTC to measure pain on a seven-point scale. Patients could therefore rate their current pain between 1 (highest possible pain level) and 7 (no pain at all). This score was also transformed to a 0-100 scale, with higher scores representing higher levels of pain. In the absence of an established cut-off level for impaired QOL, patients with a score of 1 or 2 in at least one of the three items were classified as “impaired QOL”.

Pretest

To test the comparability of the QOL scores derived with the short questionnaire and the EORTC QLQ-C30 100 consecutive patients (20 patients from each of the five treatment groups) completed both instruments, administered in random order (short questionnaire before EORTC QLQ-C30 or EORTC QLQ-C30 before short questionnaire). The resulting scores were compared within each treatment subgroup using paired-sample t-tests.

Data Analysis

Chi-Square tests were conducted to compare patients' characteristics with satisfactory and impaired QOL status (impaired quality of life was defined by a raw score of ≤ 2 in at least one of the three questionnaire items). Mean scores of global QOL and pain for patients with impaired and satisfactory QOL were compared using Student's t-test. To investigate the independent influence of gender, age, and treatment subgroup on global quality of life and pain, multivariate logistic regression analyses was performed.

Variables were collapsed using reference coding to detect those characteristics independently associated with impaired QOL. The Statistical package for the Social Sciences (Version 9, SPSS; Spss, Inc, Chicago, IL) was used for all statistical analyses.

Results

The pretest revealed that the mean global QOL scores and mean pain scores measured by the three-item questionnaire were similar to the scores obtained when these questions were asked within the EORTC QLQ-C30 questionnaire (Table 1).

In the larger study, patients' mean age was 58 years (range: 18 to 93 years), and 65% of all patients were women. Overall, we identified 254 of the 1837 (13.8%) patients to have impaired QOL. Table 2 presents characteristics of patients with impaired and satisfactory QOL prior to commencement of radiotherapy. When compared to patients with satisfactory QOL, patients with impaired QOL were significantly more likely to be of younger age (17% of those 18-29 years compared to 10.3% of those >70 years reported impaired QOL). Significantly more men (17%) than women (12.1%) reported impaired QOL. The patient groups with the highest proportion of reporting impaired QOL was treated for Advanced Cancer (31.4%) followed by those treated for cancer of the Lung/GI/H&N (17.7% with impaired QOL) (Table 2).

The mean global QOL score was 32.6 for patients with impaired QOL and 72.4 among patients in this study who reported satisfactory QOL (t -value = 30.063, $p < 0.001$). The mean pain score was 70.9 for patients with impaired QOL, compared to a mean score of 18.1 for patients with satisfactory QOL (t -value = 32.9, $p < 0.001$). Table 3 summarises the global QOL and pain scores for gender and treatment subgroups. Figure 1a+b show the global QOL and pain scores for men and women by age groups in comparison with population-based data [19]. As expected, cancer patients, on average report lower global QOL and higher pain than the general population; however, for both men and women, there is a noteworthy cross-over at older ages and cancer patients actually report higher global QOL and lower pain on average.

Results of the multivariate logistic regression analysis to predict impaired QOL are presented in Table 2. Patients older than 60 years were significantly less likely to report impaired QOL compared to patients younger than 60 years. When adjusted for age and treatment subgroup, the OR for patients with both genders were similar (OR = 0.97). For evaluation of treatment subgroup adjusted for age and sex, patients treated for LUNG/GI/H&N were selected as a reference group, since men and women are equally represented in this treatment subgroup. In comparison, patients treated for advanced cancer were significantly more likely to report impaired QOL (OR = 2.4) whereas patients treated for breast cancer were significantly less likely to report impaired QOL (OR = 0.4). The remaining two treatment groups were not significantly different from the comparison group.

Discussion

Up to 60% of all cancer patients receive radiotherapy at some stage of their illness [19]. For clinicians, it is obvious that a significant number of patients suffer from acute, impaired QOL during treatment [19], whereas others seem to improve in their QOL [22, 8]. Research, largely in the context of chemotherapy, indicates that patients with impaired QOL are not only more likely to experience marked side effects during treatment [31], but that QOL furthermore provides independent prognostic information [2,3,6,16,28]. Determining QOL at baseline and addressing QOL issues during treatment are therefore critically important to the care of the patient. More patients than ever are seen in outpatient settings, where visits are short and hurried to contain costs. An ideal screening test for QOL should be inexpensive, easy to administer, present results to the medical staff immediately and should impose minimal inconvenience to the patient, while covering relevant aspects of the patients experience [25,9]. While computerised versions of the EORTC QLQ-C 30 are a promising alternative [32], costs related to the purchase and maintenance of the computer facilities and the specialised staff needed for such facilities might impose difficulties.

In the present study, we report on the feasibility and usefulness of a very short screening instrument consisting of only three questions on QOL and pain based on the EORTC QLQ-C30 questionnaire. We demonstrated that this tool results in scores comparable to those derived if the questions are asked within the complete EORTC QLQ-C30 questionnaire and is well accepted by patients and staff. Since completion of this study, organisational problems responsible for the intermittent screening during data collection have been resolved, and the ongoing screening rate is now close to 95%. Both the preparation time necessary to introduce patients to this three-item questionnaire and the refusal rate among patients are very low. Completed questionnaires can be easily

reviewed and a score below the proposed cut-off level can be noticed by the medical and psychosocial staff immediately.

For the aim of this study, we defined a raw score of 1 or 2 in any of the three questionnaire items to represent impaired quality of life. Overall, the incidence of impaired QOL by this definition was almost 14%, which compares favourably with previous studies carried out using more time-consuming methods [12,21,29]. Although the three items are correlated with each other, they each capture distinct aspects of QOL (data not shown).

In this Austrian study, the mean global QOL score was 66.9 for the whole sample. This is somewhat lower than the 70.8 reference value in the general German population [23], very close to the 65 observed in a group of English radiotherapy patients [18] and higher than the 52.3 reported for a mixed group of American cancer patients [32], all based on the EORTC QLQ-C30. The utility of these three questions as a screening tool is evident from the mean global QOL score of 32.6 for patients identified as having impaired QOL, which is significantly lower than the 72.4 among patients reporting satisfactory QOL. The latter score corresponds well with the mean global QOL scores of 77.3 and 70.8 found in general population samples from Norway [11] and Germany [23].

In the present study, patients with impaired QOL were more likely to be younger than 60 years. In contrast, older people describe worse quality of life in the general population [11,23]. For example, in comparison to the population-based reference data from Germany [5,23], men in the age group 18-29 from our study reported a mean global QOL score of 70.7 compared to 83.6 from the general population sample, which is a reduction by 13 points. Women aged 18-29 reported a global QOL score of 64.2 in our study compared to 78.9 in the general population, a reduction of 14.7 points and

representing lower QOL levels than seen for men. Pain scores in these younger groups were considerable higher (representing more pain) than in the general population (e.g. male cancer patients aged 18-29 reported a pain score of 23.6, compared to 3.7 in the general population pain). However, pain scores in the older groups of cancer patients were somewhat lower than in the general population (e.g., women aged 60-69 reporting mean score of 22.6, compared to 23.9 for the general population). The QOL scores reported by the cancer patients older than 60 years were similar or slightly better than those of the general population (Figure 1). As Fayers points out, the expectation with which people are comparing their actual QOL might be an explanation for the relatively low QOL scores found in the older general population [5] compared to the cancer patients in the present study. Men were more likely to report impaired QOL in unadjusted analysis however, there was no significant difference in QOL between men and women in the adjusted multivariate analysis.

Looking at the results of the multivariate modeling reveals that those patients treated for Lung/GI/H&N cancer, or for advanced cancer were more likely to report worse QOL prior to commencing radiotherapy compared to other patients. Whether clinical interventions or psychosocial support can improve QOL in these patients and enhance prognosis following radiotherapy remains unknown.

The short screening questionnaire presented in this study will not replace existing, multi-dimensional QOL questionnaires in research settings or where characterization of QOL is a major focus. However as an aid to clinical practice, this three-item questionnaire offers a useful way to identify patients who may be referred for specialist, psychosocial support [4]. Fayers recommends “...a modest initial target in patient management might be to try to ensure the patients’ QOL is no worse than the average of the age and gender matched population” [5, p1333]. In the future, further evaluation of

quality of life and psychological distress will be performed at our clinic for those patients identified with impaired QOL.

Acknowledgments: The authors are grateful to the EORTC Quality of Life Study Group for granting us permission to use a modified version of the EORTC QLQ-C30 in this study.

This study was funded in part by the “medizinisch wissenschaftlicher Fonds des Buergermeisters der Stadt Wien”.

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Table 1: Pretest comparison of mean global quality of life scores (\pm standard deviation) and mean pain scores (\pm standard deviation) as measured by the EORTC-QLQ C 30 and the three-item questionnaire by treatment subgroup

Treatment Subgroup	Global Quality of Life Score				Pain Score			
	EORTC QLQ-C30	Three-item questionnaire	Paired t-test	p-value	EORTC QLQ-C30	Three-item questionnaire	Paired t-test	p-value
Breast	74.2 \pm 21.6	77.5 \pm 21.6	1.2	0.25	17.5 \pm 21.6	18.3 \pm 25.5	0.1	0.96
GU, GYN	64.9 \pm 29.4	70.8 \pm 27.5	1.5	0.14	25.8 \pm 33.9	17.5 \pm 24.5	1.3	0.21
Lung/GI/H&N	53.0 \pm 26.1	59.0 \pm 28.8	1.9	0.06	44.0 \pm 35.9	43.3 \pm 37.6	0.1	0.90
HAEM/Brain	60.4 \pm 27.1	60.4 \pm 26.5	0.0	1.00	25.0 \pm 31.3	40.0 \pm 37.2	1.6	0.11
Advanced Cancer	45.8 \pm 28.7	51.7 \pm 30.1	1.0	0.31	60.8 \pm 44.3	55.0 \pm 35.1	0.8	0.43

Abbreviations: GU = Genitourinary Cancer, GYN = Gynaecological Cancer, GI = Gastrointestinal Cancer, H&N = Head and Neck Cancer, HAEM = Haematological Malignancy

Table 2: Characteristics of patients (N=1,837) and multivariate logistic regression analysis of factors predicting impaired quality of life

	<u>Patients with</u> <u>satisfactory QOL</u>		<u>Patients with</u> <u>impaired QOL †</u>		<i>Adjusted* Odds</i> <i>Ratio (95% CI)</i>	χ^2 Test and p- value for Trend
	N=1,583	%	N= 254	%		
Age (years)	58.4		55.9			7.44, p=0.006
Median	59		56			
Range	18-93		18-93			
18-29	44	2.8	9	3.5	1.65 (0.73-3.76)	
30-39	125	7.9	23	9.1	1.42 (0.81-2.47)	
40-49	229	14.5	43	16.9	1.54 (0.98-2.42)	
50-59	417	26.3	83	32.7	1.57 (1.07-2.32)	
60-69	383	24.2	52	20.5	Reference group	
>70	385	24.3	44	17.3	0.78 (0.51-1.21)	
Sex						8.3, p=0.004
Men	532	33.6	109	42.9	Reference group	
Women	1051	66.4	145	57.1	0.97 (0.70-1.34)	
Treatment subgroup						48.9, p=0.001
Breast	655	42.4	58	23.3	0.44 (0.28-0.67)	
GU, GYN	197	12.7	30	12.0	0.90 (0.56-1.46)	
Lung/GI/H&N	288	18.6	62	24.9	Reference group	
HAEM/Brain	273	17.7	38	15.3	0.64 (0.41-1.00)	
Advanced Cancer	133	8.6	61	24.5	2.41 (1.59-3.64)	
Missing	37	2.3	5	2.0		

Abbreviations: QOL = Quality of life, GU = Genitourinary Cancer, GYN = Gynaecological Cancer, GI = Gastrointestinal Cancer, H&N = Head and Neck Cancer, HAEM = Haematological Malignancy, Missing because of uncertainty at admission.

* Multivariate logistic regression analysis with all variables adjusted for all other factors to predict the impaired QOL at commencement of radiotherapy

† Impaired QOL defined as a score of 1 or 2 in at least one of the three items of the three-item questionnaire.

Table 3: Mean global quality of life and mean pain scores, by gender and treatment subgroup

	Treatment subgroup						Treatment subgroup						Total
	Men (N = 641)						Women (N = 1196)						
	All	Breast	GU	Lung/ GI/ H&N	HAEM /Brain	Advanced Cancer	All	Breast	GU/GYN	Lung/ GI/ H&N	HAEM /Brain	Advanced Cancer	
Global Quality of Life	65.9	64.6	73.6	65.6	66.1	56.9	67.5	68.9	68.2	65.2	67.0	60.5	66.9
Pain	27.8	4.2	18.9	30.6	21.8	44.9	24.1	21.1	27.3	29.7	15.8	43.5	25.4

Abbreviations: GU = Genitourinary Cancer, GYN = Gynaecological Cancer, GI = Gastrointestinal Cancer, H&N = Head and Neck Cancer, HAEM = Haematological Malignancy

Figure 1: (a) Mean Global quality of life score (higher scores representing higher quality of life) and pain scores (higher scores representing higher pain) (General German population data compared to data obtained by the present Austrian study); males;

Figure 1 (b) Mean Global quality of life score (higher scores representing higher quality of life) and pain scores (higher scores representing higher pain) (General German population data compared to data obtained by the present Austrian study); females;