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European Journal of Cancer 37 (2001) 2349–2356

European Journal of Cancer

www.ejconline.com

Quality of life measurement in oncology—a matter of the assessment instrument?

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Received 8 May 2001; accepted 17 August 2001

Abstract

Two widely used quality of life questionnaires European Organization for Research and Treatment of Cancer Core (EORTC QLQ-C30), Functional Assessment of Cancer Therapy—General (FACT-G) were examined for their comparability using four different groups of cancer patients. During a follow-up investigation, 418 cancer patients (Hodgkin's disease, breast cancer, bone marrow transplantation (BMT), chronic lymphatic leukaemia (CLL) completed both the EORTC QLC-C30 and the FACT-G during the same session. For an illustration of the differences between the two Quality of Life (QoL) instruments, pairs of diagnostic groups were formed and their QoL scores using the EORTC QLQ-C30 and FACT-G compared. The corresponding subscales of the EORTC-QLC-C30 and the FACT-G show only low to moderate intercorrelations across all four groups of cancer patients studied. In particular, a comparison of pairs, namely Hodgkin's disease versus breast cancer patients and BMT versus CLL patients, highlights substantial differences in the corresponding subscales of the EORTC QLQ-C30 and the FACT-G. The results of the QoL investigations should not be interpreted independently of the instrument used and an interpretation of results must be based on the contents of items of the respective questionnaires.

Keywords: Quality of life; Assessment, FACT-G; EORTC QLQ-C30; Cancer; Comparison

1. Introduction

In many clinical situations in oncology, cure is impossible and treatment is mainly directed towards palliation of symptoms and/or prolongation of life. Innovative treatment regimens often do not result in substantial differences in overall survival, but are at best associated with reduced side-effects. This is supposed to reflect a gain in Quality of Life (QoL) [1,2]. A similar situation, however, might also exist in patients with a high chance of cure for their neoplastic disease. When cure rates approach 80% of cases, such as in localised stages of Hodgkin's disease, further improvement may be extremely difficult and therapeutic progress might focus on maintaining high cure rates, while reducing side-effects and improving QoL [3,4]. Thus, where the clinician needs to make a choice between available therapies with no great differences in the expected outcome, the process of decision-making is primarily driven by an anticipated gain in QoL [5].

This demands reliable instruments for the measurement of QoL. However, as there are several psychometrically valid assessment instruments which are currently in use, comparability of assessment methods across trials must be ensured. With a few exceptions [6–8], the issue of comparability has not been dealt within the literature so far.

This paper is concerned with two of these QoL instruments, the European Organization for Research

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0959-8049/01/$ - see front matter
PII: S0959-8049(01)00307-0

and Treatment of Cancer Quality of Life Core Questionnaire (EORTC QLQ-C30) and the Functional Assessment of Cancer Therapy—General Scale (FACT-G), which are probably the most widely used cancer-specific QoL instruments today. Both have been internationally validated and follow a similar general concept, namely a modular setup with a generic core questionnaire in combination with site-specific modules [9]—e.g. for use with breast cancer [10], ovarian cancer [11] or patients with brain tumours [12]. In both cases, the generic part of the instrument (EORTC QLQ-C30, FACT-G) has a domain (subscale) structure allowing the presentation of outcome as a profile. Such a profile shows domains in which patients perform well or fairly well and others in which they perform less well.

There is almost complete agreement between the two instruments in the nomenclature of the most important domains, namely physical (EORTC physical functioning versus FACT physical well-being), emotional (EORTC emotional functioning versus FACT emotional well-being), social (EORTC social functioning versus FACT social well-being) and functional/role (EORTC role functioning versus FACT functional well-being). This similarity of names suggests a similarity of the aspects investigated.

Nevertheless, in a recently published study on patients with breast cancer and Hodgkins's disease, we found considerable differences between the EORTC QLQ-C30 and FACT-G [8]. In particular, corresponding subscales of the two instruments were found to measure partially different aspects of QoL. However, the study was limited to two diagnostic groups and was mainly focused on methodological issues. This paper builds upon and extends this study. It is based on an extended sample of four groups of cancer patients: breast cancer, Hodgkin's disease, chronic lymphatic leukaemia (CLL) and bone marrow transplantation (BMT). Some data of the first two groups were already used in the report mentioned above.

This new investigation pursues two aims: to study the generalisability of our previous findings in a larger sample group and to investigate the practical consequences for clinical applications. More specifically, the following two questions have been explored:

- Do the inconsistencies between the EORTC QLQ-C30 and FACT-G previously found hold true across a variety of groups of cancer patients (CLL, BMT, breast cancer, Hodgkin's disease)?
- If this is the case, do these inconsistencies result in (seemingly) contradictory conclusions when comparing different groups of patients? In this context, the four diagnostic groups serve only to illustrate the differences between the two QoL assessment instruments, while a comparison of the groups *per se* is not the goal of this study.

2. Patients and methods

2.1. Sample

A total of 418 oncological outpatients (122 patients with breast cancer, 135 with Hodgkin's disease, 97 with CLL and 64 BMT patients), all of whom had previously been treated at Innsbruck University Hospital, were contacted at the time of their follow-up visits at the respective special oncological clinics. It should be noted that only three of the groups refer to cancer diagnoses, while the fourth group reflects a treatment modality.

Some data of the first two diagnostic groups (breast cancer, Hodgkin's disease) were already used in our previous study [8]. Some aspects of the BMT sample have been discussed by Kopp and colleagues [13].

Patients were asked to fill in both the EORTC QLQ-C30 and the FACT-G questionnaires, in addition to a form for collecting sociodemographic data. Out of the 418 patients approached, 381 (91.1%) agreed to participate, completed the questionnaires and could thus be enrolled in this study.

To determine how differences in aspects of QoL assessed by the two instruments are reflected by the oncological groups investigated, we paired off the groups as follows: CLL versus BMT patients, Hodgkin's disease versus breast cancer. It should be stressed that the purpose of the approach was not the comparison of QoL in the different groups, but a comparison of the two QoL assessment instruments. This means that potential discrepancies of the instruments reflected by the comparison of the diagnostic groups may similarly occur when comparing other groups, e.g. different treatment modalities.

2.2. Quality of life instruments: EORTC QLQ-C30-FACT-G

Both are generic QoL-instruments with a main focus on cancer patients. The two questionnaires are used worldwide and have been shown to have good validity and reliability properties both for the original English instrument and the translations into various languages, including German [12,14–22].

There are only minor differences between the EORTC QLQ-C30 and FACT-G pertaining to the number of items (30 items in the EORTC QLQ-C30 and 27 items in the FACT-G) and in the type of scales employed (EORTC QLQ-C30: four-point Likert scale and seven-point numerical analogue scale; FACT-G: 5-point Likert scale).

Both questionnaires have four subscales each, with the corresponding subscales having similar names; these pertain to the physical, social, emotional and functional/role domains. It should be noted that the corresponding subscales do not have identical labels: physical

functioning (EORTC QLQ-C30) versus physical well-being (FACT-G), social functioning versus social/family well-being, emotional functioning versus emotional well-being and role functioning versus functional well-being. The EORTC QLC-C30 has two additional subscales, namely: 'cognitive functioning' and 'global quality of life'. However, in contrast to FACT-G, no provision is made in this questionnaire for a total score.

Individual somatic symptoms, such as fatigue/vomiting, pain, etc., are placed under separate symptom scales in the EORTC QLQ-C30. In the FACT-G, questions regarding individual symptoms are subsumed under the subscales of physical and functional well-being. A full description of each of these measures can be obtained from the key references [14,15].

2.3. Data analysis and statistical methods

Subscores of the EORTC QLQ-C30 and the FACT-G were computed according to the instructions of the developers (all scales, except for the EORTC symptom scales, are scored in such a way that higher values mean higher QoL). In addition, to facilitate comparisons between scales, transformed FACT subscores were determined by converting the original values linearly to a range of 0–100 (0 = poorest, 100 = best QoL), analogous to the procedure for the QLQ-C30.

The interrelations between the corresponding subscales of the two instruments (question 1) were explored by correlation analysis (Pearson r). The internal consistency (Cronbach's α) of the subscales served as an approximate upper limit for the correlation r of corresponding subscales [23] and thus as a criterion for assessing agreement of subscales ($r \approx \alpha$: good agreement, $r << \alpha$: poor agreement).

For group comparisons with respect to the QoL subscales, the Mann–Whitney U test was used. To quantify differences between groups, effect sizes were determined (difference of group means divided by the joint standard deviation of the groups).

As the main objective of this study was not a comparison of the QoL of patients with different types of cancer, but rather the comparability of the instruments employed, no adjustments for sociodemographic and/or clinical differences between groups were made. However, the effect of age was studied in separate analyses of covariance.

3. Results

3.1. Patient characteristics

The sample consisted of 381 cancer patients: 56 BMT-patients (mean age 34.0 years ± standard deviation (S.D.) 9.7), 118 patients with breast cancer (mean age 53.1 years ± S.D. 8.1), 126 patients with Hodgkin's diseases (mean age 44.6 years ± S.D. 14.0) and 81 patients with CLL (mean age 67.1 years ± S.D. 10.3). The average time period since the initiation of treatment was 6.4 ± S.D. 5.2 years for the total sample.

A detailed description of the sociodemographic and clinical characteristics of patients is given in Table 1.

The four groups of oncological patients investigated differ from each other in their sociodemographic and clinical data. However, since these differences are not relevant for the questions raised in this study, they are not considered further.

3.2. Correlations of the EORTC QLQ-C30 and FACT-G subscales in the four groups

In Table 2, Pearson correlation coefficients for the pairs of corresponding QLQ-C30 and FACT-G subscales (QLQ-C30 'physical functioning' and FACT-G 'physical wellbeing', etc.) are shown, both for the total sample and for the individual groups.

In the total sample, correlations between the QLQ-C30 and FACT-G subscales for the *physical* domain were fairly high ($r = 0.64$, to be compared with Cronbach's alpha for the two subscales, $\alpha = 0.76$ (EORTC) and $\alpha = 0.88$ (FACT)). For the *emotional* and the *role/functional* domains, however, correlations of corresponding QLQ-C30 and FACT-G subscales were clearly lower than expected for scales that measure the same content ('emotional': $r = 0.46$, compared with $\alpha = 0.81$ and $\alpha = 0.62$, 'role/functional': $r = 0.59$, compared with $\alpha = 0.86$ and $\alpha = 0.81$). Most conspiciously, in the *social* domain the correlation between corresponding subscales was only $r = 0.24$, compared with $\alpha = 0.77$ and $\alpha = 0.58$.

Basically the same pattern of correlations is found across all four groups studied. The low correlation between FACT-G and QLQ-C30 in the social domain is reflected most markedly by the breast cancer patients ($r = 0.06$) and least by those with BMT ($r = 0.37$), while for the emotional domain it is the other way around (BMT: $r = 0.21$, breast cancer: $r = 0.57$). In the physical domain, the correlation coefficient for the BMT patients was lower than for the other groups. Finally, in the role/functional domain, only patients with breast cancer and Hodgkin's disease showed a considerably lower correlation between the corresponding QLQ-C30 and FACT-G subscales than would be expected for scales measuring the same construct ($r = 0.46$, compared with α values between 0.72 and 0.88).

In summary, these results indicate that there are serious inconsistencies between corresponding subscales of the EORTC QLQ-C30 and FACT-G across all four groups; these discrepancies will be considered in greater detail in the following section.

Table 1
Sociodemographic and clinical data

		Patients with Hodgkin's disease	Breast cancer patients	BMT patients	Patients with CLL
Number		$n=126$	$n=118$	$n=56$	$n=81$
Age (years)	Mean (S.D.)	44.6 (14.0)	53.1 (8.1)	34.0 (9.7)	67.1 (10.3)
	Range	18.8–78.3	30.0–72.0	17.3–56.8	41.0–89.0
Sex (%)	Female	50.8	100.0	39.3	40.7
	Male	49.2		60.7	59.3
Marital status (%)	Single	16.8	14.4	33.9	6.2
	Married/with partner	78.4	71.2	58.9	67.9
	Divorced	2.4	5.1	3.6	4.9
	Widowed	2.4	9.3	3.6	21.0
Education	Elementary school	46.3	43.2	37.1	46.8
(highest achieved level) (%)	Completed Apprenticeship	35.8	42.4	40.6	38.6
	High school	6.5	11.0	12.1	10.1
	University	11.4	3.4	10.2	4.5
Stages (%)	Stage I	15.1	42.4		Rai 0 46.5
	Stage II	45.2	50.0		Rai 1 18.0
	Stage III	25.4	3.4		Rai 2 31.1
	Stage IV	14.3	4.2		Rai 3 III + IV 4.3
Treatment modalities (%)	Chemotherapy	69.8	49.1	100.0	44.4
	Radiotherapy	75.4	43.2	100.0	0.0
Time since initial	Mean (S.D.)	9.1 (7.0)	5.0 (4.9)	5.4 (3.9)	4.8 (3.2)
diagnosis (in years)	Span	1.0–33.0	1.0–22.0	1.7–18.1	1.0–15.6
Time since	Mean (S.D.)			3.7 (3.2)	
transplantation (in years)	Range			1.0–10.8	

BMT, bone marrow transplantation; CLL, chronic lymphatic leukaemia; S.D., standard deviation.

Table 2
Correlations coefficients (Pearson r) between the corresponding EORTC QLQ-C30 and FACT-G subscales within different groups of cancer patients[a]

	Correlations between			
	EORTC physical and FACT physical	EORTC emotional and FACT emotional	EORTC social and FACT social	EORTC role and FACT functioning
Patients with CLL ($n=81$)	0.75	0.52	0.23	0.68
BMT patients ($n=56$)	0.43	0.21	0.37	0.70
Breast cancer patients ($n=118$)	0.63	0.57	0.06	0.46
Patients with Hodgkin's disease ($n=126$)	0.71	0.47	0.25	0.46
Total sample ($n=381$)	0.64	0.46	0.24	0.59

EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Core Questionnaire; FACT-G, Functional Assessment of Cancer Therapy—General; CLL, chronic lymphatic leukaemia; BMT, bone marrow transplantation.
[a] All correlation coefficients greater than 0.2 are statistically significant ($P<0.01$).

3.3. Comparing QoL in different groups of cancer patients with the two instruments

The QoL scores assessed by both inventories for the four groups of patients with CLL, BMT, Hodgkin's disease and breast cancer are given in Table 3a (CLL, BMT) and Table 3b (Hodgkin's disease and breast cancer).

3.3.1. Comparison of BMT patients and patients with CLL (see Fig. 1, FACT-subscales were converted to a range from 0 to 100)

When measured with the EORTC QLQ-C30, patients with CLL had significantly lower average scores in the areas of physical functioning (effect size (ES): −0.519) and role functioning (ES: −0.201) than the BMT patients. In the area of social functioning (ES: 0.481), however, there was a significantly higher average score in the CLL group. No significant differences between the groups could be found for the other subscales.

In the FACT-subscales, the only significant difference between the BMT and CLL-patients was seen in the emotional domain where the BMT-group had a markedly lower score (ES: 0.787).

In an analysis of covariance for the joint sample of BMT and CLL patients, the effect of age was examined further. It was found that age had a strong and statisti-

Table 3
(a) Subscales EORTC QLQ-C30 and FACT-G, CLL and BMT patients; (b) subscales EORTC QLQ-C30 and FACT-G, patients with Hodgkin's disease and breast cancer

a.	Patients with CLL		BMT patients		Effect size
	Mean	S.D.	Mean	S.D.	
EORTC QLQ-C30 functioning scales					
Physical functioning	73.1	24.4	85.0	20.6	−.519***
Emotional functioning	69.8	20.1	66.4	27.8	.144
Social functioning	81.8	23.9	68.8	31.0	.481*
Role functioning	68.4	30.6	75.0	35.7	−.201*
Cognitive functioning	74.2	24.7	77.1	29.1	−.109
Global quality of life	64.9	21.9	68.2	24.0	−.145
FACT-G subscales					
Physical well-being	21.8	5.4	21.1	7.0	.115
Emotional well-being	18.8	3.9	15.6	4.3	.787***
Social well-being	20.2	3.9	20.1	5.3	.022
Functioning well-being	19.1	6.3	20.5	5.7	−.231
Total score	84.6	15.1	84.5	16.6	.006

b.	Patients with Hodgkin's disease		Breast cancer patients		Effect size
	Mean	S.D.	Mean	S.D.	
EORTC QLQ-C30 functioning scales					
Physical functioning	89.2	16.6	88.5	15.1	.044
Emotional functioning	74.7	23.5	73.4	23.4	.055
Social functioning	88.2	22.4	88.8	20.7	−.028
Role functioning	86.8	23.0	86.6	23.2	.009
Cognitive functioning	89.2	18.5	87.2	22.9	.096
Global quality of life	81.8	17.6	71.3	23.9	.503***
FACT-G subscales					
Physical well-being	25.5	3.8	24.8	4.6	.166
Emotional well-being	20.3	2.6	18.8	4.4	.418*
Social well-being	22.2	3.4	20.6	5.1	.372*
Functioning well-being	22.1	3.7	21.5	5.4	.130
Total score	97.0	10.2	92.6	14.8	.348*

***$P \leqslant 0.001$, *$P \leqslant 0.05$. EORTC QLQ-C30, European Organization for Research and Treatment of Cancer Core Questionnaire; FACT-G, Functional Assessment of Cancer Therapy—General; CLL, chronic lymphatic leukaemia; BMT, bone marrow transplantation.

cally highly significant effect in the physical and role/functional dimensions when measured with the EORTC QLQ-C30 ($P < 0.001$), whereas it had a much weaker, statistically non-significant effect in the FACT-G ($P > 0.05$). No age-effect was observed in the social domain.

3.3.2. Comparison of patients with Hodgkin's disease with breast cancer patients (see Fig. 2; FACT-subscales were converted to a range from 0 to 100)

The average scores for the individual domains of the EORTC QLC-C30 are equally high in both groups. Only in the subscale 'global quality of life' do patients with Hodgkin's disease have significantly higher scores than breast cancer patients (ES: 0.503).

However, the QoL scores as assessed by the FACT-G questionnaire of patients with Hodgkin's disease are generally higher than those of breast cancer patients, with significant differences between the two groups in the subscales of emotional well-being (ES: 0.418), social and family well-being (ES: 0.372), as well as in the total score (ES: 0.348).

4. Discussion

QoL assessment by means of self-administered questionnaires has now become a routine part of oncological studies and is steadily gaining importance as an evaluation criterion in clinical decision-making [24–26]. A valid and reliable measurement of QoL is therefore of special importance. As no one particular assessment instrument has come to be accepted as a gold standard, but rather a number of validated questionnaires are employed worldwide, comparability of these instruments has to be considered crucial [8,27].

In this paper, two such questionnaires were subjected to a critical comparison, the EORTC QLQ-C30 and the FACT-G, probably the two most widely used oncological QoL instruments. The similar structure of the two

questionnaires and, in particular, the resemblance in the names of the four main dimensions (physical, functional/role, emotional and social) encourages the assumption that there is also a similarity of content. The findings of this study show, however, that this assumption cannot be upheld and that a comparison of the EORTC QLQ-C30 subscales with the corresponding FACT-G subscales (e.g. 'EORTC social functioning' and FACT-G 'social and family well-being' subscale) would lead to contradictory results.

The results of this study confirm those of our original investigation [8]. However, they go beyond these previous findings in two respects. Firstly, our data include two additional groups of patients and we showed that the same pattern of inconsistencies between the two instruments is observed across all four groups studied. Secondly, by contrasting the QoL profiles of pairs of groups evaluated with the EORTC QLQ-C30 and the FACT-G, we were able to demonstrate that the discrepancies between the instruments result in seemingly contradictory conclusions when making comparisons between different groups of cancer patients.

For a more detailed discussion of the results, we considered the four domains (physical, emotional, social, functional) separately. For each domain, we contrasted *observed* differences between the two instruments (as reflected by the pairs of groups studied) with *hypothesised* differences as suggested by an inspection of the contents of the individual items. It has to be emphasised

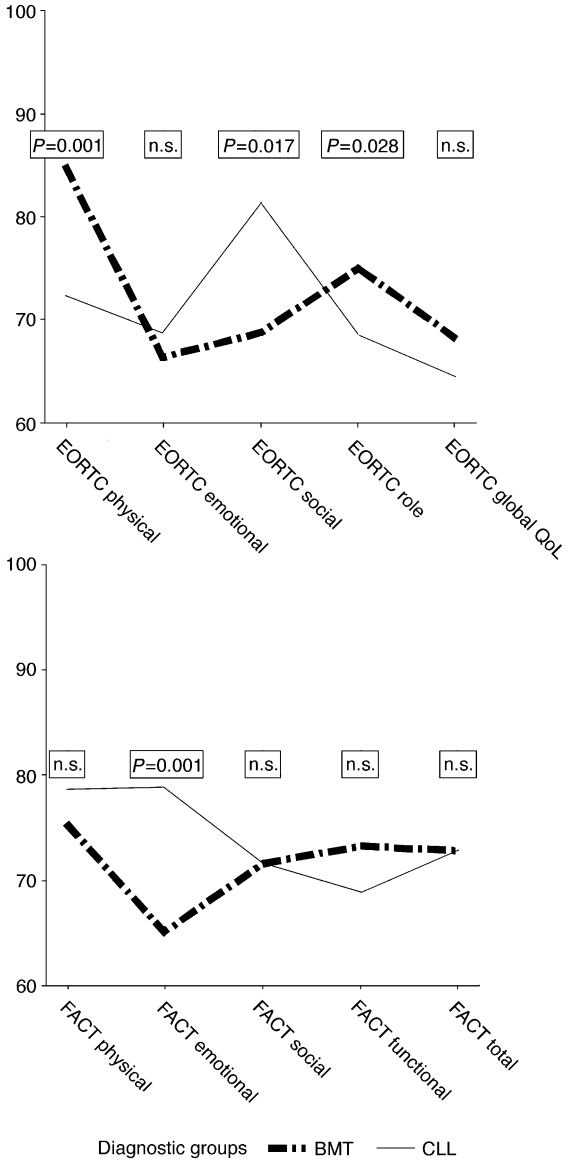

Fig. 1. European Organization for Research and Treatment of Cancer Core (EORTC QLQ-C30) and Functional Assessment of Cancer Therapy—General (FACT-G) subscales: bone marrow transplantation (BMT)-patients and patients with chronic lymphatic leukaemia (CLL) FACT-G scores are converted to the range of 0–100 by linear transformation. n.s., non-significant.

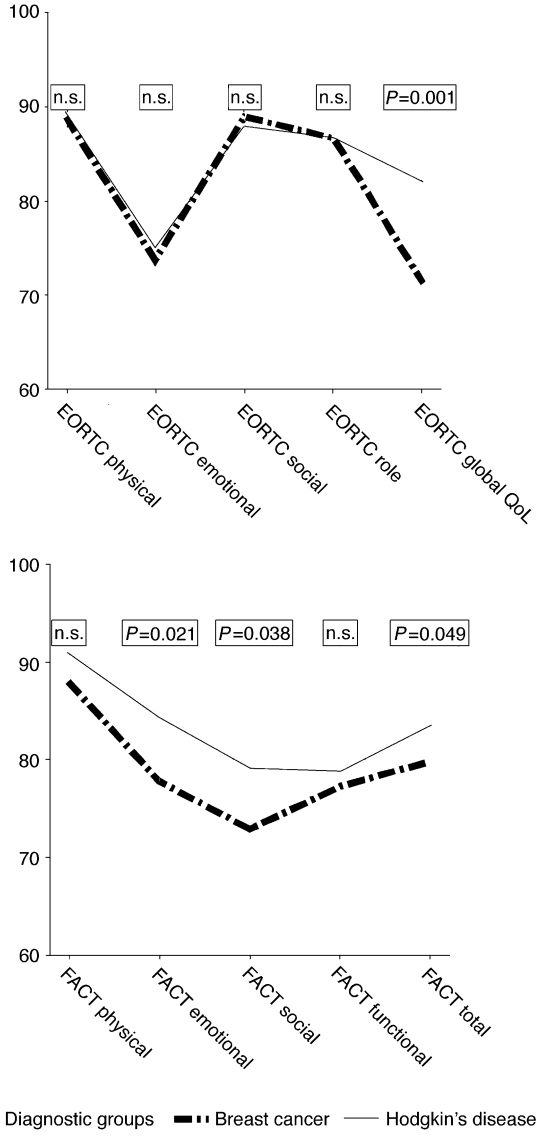

Fig. 2. EORTC QLQ-C30 and FACT-G subscales: patients with Hodgkin's disease and breast cancer patients. FACT-G scores are converted to the range of 0–100 by linear transformation.

again that this study was not designed to investigate QoL differences between various groups of cancer patients, but how they are reflected by the two QoL questionnaires.

In the *physical* dimension, differences between the two instruments are highlighted by a comparison of the groups BMT and CLL. In the EORTC subscale 'physical functioning', the scores of the CLL patients are considerably lower than those of the BMT patients, but there were no such differences in the corresponding subscales of the FACT questionnaire. On examining the items individually, it becomes apparent that the 'physical' subscale in the EORTC scale measures basic physical functions and physical efficiency, while the corresponding FACT dimension focuses primarily on physical symptoms such as fatigue and pain. As shown in the analysis of covariance, a key parameter in this context is age (on average, CLL patients were more than 30 years older than BMT patients). The effect of advanced age on physical capacities is reflected by the lower scores of the EORTC physical functioning scale, whereas the FACT-G subscale 'physical wellbeing' does not show this pattern.

In the *emotional* dimension, the FACT scores of the BMT patients are lower than those of CLL patients and the scores of breast cancer patients are lower than those of patients with Hodgkin's disease. These differences, however, are not found when using the EORTC questionnaire. Scrutinising the contents of the subscales, it becomes clear that the EORTC emotional functioning domain refers primarily to the emotional condition of the patient (irritability, tension, depression), whereas the FACT emotional well-being subscale addresses, in particular, existential issues (worries about the future or death). This, again, illustrates that the domains on the respective instruments measure different aspects of QoL. It may also explain why patients having undergone a BMT, which is a life-threatening procedure, score lower on the FACT instrument [28].

When comparing the two instruments in the *social* domain, the EORTC scores of the BMT patients are found to be significantly lower than those of CLL patients, while no such differences can be observed in the corresponding FACT scale. A closer look at the items evaluated in this dimension shows that the FACT-G is primarily directed at aspects of social support. In contrast, the items on the social functioning subscale of the EORTC QLQ-C30 are relevant to limitations in family and social life caused by physical complaints. The analysis of covariance shows that age is not a relevant factor in this context. However, as BMT patients had to undergo a much more incisive medical intervention than CLL patients, including isolation for a long period of time, it is fair to assume that BMT patients are more severely affected in their social functioning even years after transplantation. Indications for this have been previously reported [29].

In the area of 'function' *or* '*role*', a comparison of BMT and CLL patients also shows differences between the two inventories. CLL patients achieved significantly lower scores in the EORTC 'role' dimension than BMT patients. Once again, no such differences were found in the corresponding dimension of the FACT-G.

Role in the EORTC QLQ-C30 scale captures limitations in role functioning with reference to work and leisure activities. The corresponding FACT-G dimension is many-faceted and comprises, for instance, the ability to enjoy, to work, to cope with the illness, as well as work satisfaction. Similar to the physical domain, differences between the CLL and BMT patients in the EORTC role domain can be explained by the fact that the former group of patients, due to their higher age, are markedly more limited in their role functioning than younger BMT patients. This effect was confirmed by the analysis of covariance.

For practical purposes, our study was based upon an investigation of the QoL of four specific groups of oncological patients. It is quite possible that the results obtained may be reproduced for other groups of cancer patients, so that no generalisation to all cancer patients can be made at this point. This, however, should not distract the fact that the corresponding dimensions in the two inventories do not measure the same thing.

For the user of these inventories, the following consequences arise from our findings. First, when selecting a QoL instrument, the investigator should not simply rely on the names of the subscales or domains, but must also take into account the contents of the individual items.

Second, it should be noted that the same applies for the interpretation and comparison of the study results. When a particular research question has been investigated in different studies, using either the EORTC QLQ-C30 or the FACT-G for QoL assessment, inconsistent findings may be largely due to the above-mentioned differences between the two assessment instruments rather than to true clinical differences, such as treatment modalities, patient characteristics, etc.

In this investigation, we confined ourselves to a comparison of only two QoL instruments, namely the EORTC QLQ-C30 and FACT-G. It is likely, however, that the problem of compromised comparability between the instruments extends to other generic QoL inventories as well. Further comparative research concerning QoL instruments is needed in order to provide the user with information on the differences of the individual questionnaires and recommendations regarding their specific range of application.

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