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Patient preference for either the EORTC QLQ-C30 or the FACIT Quality Of Life (QOL) measures: a study performed in patients suffering from carcinoma of an unknown primary site (CUP)

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Abstract

The objective of this study was to examine and compare two core measures of Quality Of Life (QOL) used in cancer clinical trials: the European Organisation for Research and Treatment of Cancer QOL Core Questionnaire 30 (EORTC QLQ-30) and the Functional Assessment of Chronic Illness Therapy (FACIT), in order to identify which one patients have the strongest preference for using. 68 patients suffering from Carcinomas of an Unknown Primary site (CUP) were recruited in a multicentric study; all of them completed both questionnaires, administered in a randomised manner. The criteria were the percentage of preferences, and four indicators of acceptability. The results indicated that an equal proportion of patients preferred the QLQ-C30 (19%) and FACIT (19%). 54% of patients felt both questionnaires were acceptable. All the indicators of acceptability favoured the QLQ-C30. Analysis of open-ended questions shed light on the difficulties encountered by the patients. As no significant preference was observed for one of the questionnaires, the QLQ-C30 was chosen on the basis of its significantly better acceptability criteria.

Keywords: Quality Of Life; FACIT; QLQ-C30; Carcinoma of an Unknown Primary site; Preference

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1. Introduction

Choosing the most appropriate Quality Of Life (QOL) measure in clinical research is first and foremost dependent on the study objective. This objective may require focusing on one QOL domain, for instance, physical or social functioning or on disease-specific domains. Whatever the ultimate aim, the content of the measure must elicit a response to the question at issue. However, according to Leplège and Hunt, "the assessment of QOL measures too often has been based on arguments of authority rather than original debate" [1]. The problem of selecting measures is often complicated by the fact that many measures are frequently developed and validated in only one country and therefore this restricts the use of measures in some countries. When trials are conducted in French-speaking countries, it is often challenging to know which is the most suitable measure to select, especially for cancer types with a poor prognosis, such as Carcinomas of unknown primary (CUP). These represent a group of heterogeneous tumours that share the unique clinical characteristic of metastatic epithelial disease with no identifiable origin at the time of therapy. Prognosis is generally poor, with a median survival time of approximately 8 months [2]. Furthermore, the benefit of chemotherapy over best

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supportive care is still unknown and the optimal chemotherapy regimen remains to be determined [3]. Since 1998, the French Study Group for Carcinomas of unknown primary site (GEFCAPI) has developed research programmes on the biology, treatment and quality of life of patients with CUP.

There are mainly two cancer-specific measures which could be suitable for a French population: the QOL Core Questionnaire 30 (QLQ-C30) designed by the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Group [4], the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire [5]. They adopt a modular approach based on a core questionnaire and cancer-site specific modules. The most frequently used measure is the FACT-G in the United States of America (USA) and QLQ-C30 in Europe and Canada [6]. The original design of the QLQ-C30 was based on interviews of oncology experts. Developed in 1991, it initially comprised of 36 items, and has been through several generations of development over the late 1980s and early 1990s with patients informing about subsequent revisions in large-scale international psychometric testing. Revisions included, for example, improvements in the scales and resulted in the present 30-item measure (EORTC QLQ-C30 version 3), now the most widely used measure in oncology. In contrast, the design of the FACT-G was based on interviews with both patients and oncology experts. The version developed in 1993 comprised of 28 items (version 2). Subsequent revision resulted in version 3 with 33 items. A fourth version named FACIT (Functional Assessment of Chronic Illness Therapy) included several modifications in order to improve the quality of the questionnaire and was proposed at the 1997 International Society of QOL (ISOQOL) meeting [7]. Regardless of the different versions, the form and content of the QLQ-C30 and the FACT-G are different. The QLQ-C30 uses questions, while the FACT-G uses statements. Items are more often negatively worded in the QLQ-C30 than in the FACT-G. Kemmler [8] compared the QLQ-C30 (33 item version) and the FACT-G (version 3) in a sample of 244 patients suffering from breast cancer or Hodgkin's disease. He demonstrated that the two measures cover markedly different aspects of QOL, although there is also a fair amount of overlap, and that the sub-scales of the two instruments are not directly comparable, despite their similar name.

Two features characterise the differences in content: (a) corresponding domains do not cover similar aspects of the domain, the number of items and/or subscales are different and the items do not address the same implications. For example, 17 items concern physical domains in the QLQ-C30: five in the Physical Functioning subscale and 12 for symptom subscales. They correspond to the usual questions the clinician asks a patient during a medical examination in order to assess his/her physical condition and any sustained adverse treatment effects. All the seven physical items in the FACT-G concern one sub-scale, Physical Well-Being. Mostly, they concern what the patient feels, such as 'I am bothered by the side effects of treatment', or 'I feel ill', rather than objective statements such as 'Do you need help with eating, dressing...?', or 'Do you have any trouble taking a long walk?' as used in the QLQ-C30. This difference in perspective means that the two physical domains are not directly comparable. Another example concerns the Global QOL sub-scale. In the QLQ-C30, the Global QOL score is the sum of two items, whereas it is the sum of all the items in the FACT-G. (b) the two measures cover markedly different facets of QOL: e.g. the Social-Family domain is poorly represented in the QLQ-C30, while the cognitive domain is poorly represented in the FACT-G.

The question therefore remains as to which QOL measure is most appropriate to use in our clinical trials with CUP? We therefore conducted this study in which we asked the patients to express their preferences for the measure which best described their state of health, and then to assess the perceived acceptability of the two measures. No such study had been published at the time we undertook our study, although subsequently a communication presented at the ISOQOL meeting in 2000 [9] compared the FACT-G (v 3) with the EORTC-QLQ-C30 and the FLIC and showed that most patients preferred QLQ-C30 (37.4%). A multicentric prospective study was therefore designed, whereby cancer patients were administered the two measures and specified their preference for either of the two QOL measures. This information was then used in an advisory manner for all future prospective trials conducted by the GEFCAPI group.

2. Patients and methods

2.1. Patients

The study population consisted of patients over 18 years of age, with a CUP regardless of the site of metastases, who were being followed-up at scheduled consultations, irrespective of the treatment stage. The performance status, as measured by the World Health Organization (WHO) index [10], had to be less than 3, patients were to be free of obvious cognitive disorders and able to understand written and spoken French. The clinician explained the objective of the study to all patients who then gave their consent to participate.

2.2. Instruments

The main characteristics of the two core questionnaires are presented in Table 1. The QLQ-C30

Table 1
The two scales: content and form

	QLQ-C30 (v. 3) (30 items)	FACIT (27 items)
Source of items	Medical experts	Medical experts and patients
Content		
Sub-scales:		
Number	**5**	**4**
Description	Physical F (5 items) Social F (2 items) Emotional F (4 items) Cognitive F (2 items) Role F (2 items)	Physical WB (7 items) Social/family WB (7 items) Emotional WB (6 items) Functional WB (7 items)
Global QOL	Global QOL (2 items)	Weighted sum (27 items)
Symptom scales: no.	**9**	**0**
Isolated item	**1** (financial impact)	**0**
Form		
Negative wording	28/30	13/27
Syntax structure	questions	statements

QLQ-C30, QOL Core Questionnaire 30; v. 3, version; FACIT, Functional Assessment of Chronic Illness Therapy. F, Functioning; WB, Well-Being; QOL, Quality Of Life.

comprises five functional subscales (physical, role physical, emotional, cognitive, and social), a global health status, nine symptom subscales, and one isolated item. Results are based on 15 scores ranging from 0 to 100, 0 indicating poor QOL and 100 excellent QOL for the functional subscales, while 0 and 100 indicate ‘not at all’ and ‘very much’, respectively, for the symptom scales.

With regard to the FACT-G, the developer felt that the modifications between versions 3 and 4 (FACIT), did not compromise the demonstrated reliability and validity of the questionnaires and recommended that all investigators should use the new version. Although the modifications had yet to be translated into French at the time of the study, preference was given to the FACIT version. FACIT comprises 27 items covering four domains: Physical Well-Being, Social/Family Well-Being, Emotional Well-Being and Functional Well-Being. Changes from FACT-G (version 3) to the FACIT scale were as follows: (a) the relationship with the doctor subscale was eliminated; (b) subscale items used for weighting were excluded; (c) item wording was changed in two cases (GS7, GE2); (d) two negatively-stated items became positively-stated (GS1, GS5). To obtain a French version of the FACIT scale, we began with the French text of the FACT-G (version 3): the two newly-worded items (GS7, GE2) were translated from the original English version, using the Bonomi forward and back translation procedure [11]; items GS1, GS5 were modified using the same procedure as (c). Nevertheless, two problems arose. Three items (GP4, GP7, GE5) used French-Canadian words that are not used in France or that may not be understood by patients with a low level of education. The corresponding source items in English were therefore translated into French, using the Bonomi procedure. In addition, two items were considered particularly intrusive, for both cultural reasons and due to the very poor prognosis of cancer implied by the way these items were worded: item GE6 (‘I am worried that my condition will get worse’) and item GE5 (‘I worry about dying’). Item GE6 was removed rather than GE5 because in the third version of FACT-G, it was not taken into account for the Emotional Well-Being score.

2.3. Method

All the investigating oncologists in the GEFCAPI group were invited to participate in this study. The questionnaires were administered in the outpatient units during patient visits. The clinician explained to the patient the purpose of the study, and why they were being asked to state which of the two QOL questionnaires they preferred. The information letter given to the patient requested: “please, state which of the two scales best describes your state of health, so that your opinion can be taken into account [...] in the evaluation of the results of treatments and their impact on your quality of life”. All patients were required to give their oral consent (written consent for a QOL study is not required in France). The two questionnaires were administered in a randomised order, performed in the Gustave Roussy statistical department using stratification by centre. A standard ‘debriefing’ form, as developed by the authors of the Medical Outcome Study-Short Form 36 (MOS-SF36), was used to record items the patient felt were confusing, inadequately worded or intrusive. Two open questions allowed patients to comment freely on their preference for one or other questionnaire and add questions they would like to be included. Demographic and disease-related data, such as performance status, metastatic site, time since diagnosis were recorded by the clinician.

2.4. Data analysis and statistical methods

The number of patients required was based on a comparison of the percentage of preferences given for QLQ-C30 (Π_Q) or FACIT (Π_F). The number of preferences needed to yield a difference $\geqslant 15\%$, with a P value $=0.05$ and a $(1-\beta)$ power equal to 80%, for a two-sided test, had to be obtained from 60 individuals based on the assumption that 80% of the patients would express their preference for one of the two scales according to Machin tables [12]. 60 patients was considered the minimum number required and it was agreed that more patients would be included, if possible. The non-parametric McNemar test was used for the comparison. The acceptability of a questionnaire refers to its face validity [13]. The usual criteria were used to study the two questionnaires: the percentage of refusals, the compliance rates, and the percentage of inadequately-worded and intrusive items. In order to obtain a global indicator for patients completing the questionnaires, we summarise the three latter criteria: the items were defined as ‘difficult’ if they were not completed and/or were considered inadequately-worded or intrusive, and if such was the case for at least 10% of the patients. Patients' comments were analysed for content according to the different themes raised by the patient concerning the interest, the limitations and the omissions in the two questionnaires.

To confirm the validity of the version used in our study, we assessed the psychometric properties of the French FACIT using the multi-trait/multi-item analysis program [14]. As complete data were only available for 28% of patients, we used the option half-scale which imputes a value for missing items if the subject completes at least 50% of the items in the subscale. This value is person-specific and equals the mean response value across completed items within a subscale.

Table 2
Patients' characteristics ($n=68$)

Gender: male	44 (65%)		
Age (years): mean, (range)	56 (21–77)		
Time from diagnosis (months) (median (range))	4 (1–83)		
Site of metastases (% of patients)			
Liver	26	Bone	21
Nodes	25	Brain	9
Lung	22	Other	17
Performance status (ECOG)			
0	13 (19%)		
1	34 (50%)		
2	21 (31%)		
Treatment:			
On treatment	63 patients[a]		
Completed	4		
Due treatment	1		

ECOG, Eastern Cooperative Oncology Group.
[a] With chemotherapy: 78%.

3. Results

3.1. Patients' characteristics

68 patients treated in seven centres in France were entered into the study between May 1998 and October 1999. The median age was 57 years, with 65% being male. Metastases were located mainly in the liver, lymph nodes, lungs and bones (Table 2). Patients with brain metastases (6 cases) did not present any cognitive disorders when assessed by the clinician during the consultation. Performance status, according to WHO criteria, was good (grade 0 or 1) in 69% of patients. All but 5 patients were still undergoing treatment (chemotherapy in 78% of the cases). One patient after reading the two questionnaires refused to complete them: he was against completing items about sexuality and death. This case was considered as missing data in the analysis.

3.2. Psychometric properties of the FACIT scale

The psychometric properties of the French version were studied in the 68 patients. Satisfying results were obtained regarding responsiveness, reliability and convergent and discriminant validity (Table 3). Only one item was unsatisfactory, item GE2 (‘How I am coping with my illness’) because of its poor item-internal consistency demonstrated by the low correlation with its subscale (Emotional Well-being).

3.3. Preference

65 patients completed the preference item and three did not (Table 4). Only 38% of the patients expressed their preference for one of the two measures. A similar number of patients preferred the QLQ-C30 (13 patients) and FACIT (13 patients). One or the other measure was found to be relevant for 54% of the patients. 2 patients found that neither measure was relevant. The administration order of the two measures had no significant effect on the results.

3.4. Acceptability

All the eligible patients agreed to participate in this study. Only 1 patient, mentioned above, refused to complete the questionnaires after having read them. The percentage of unanswered items was significantly higher for the FACIT questionnaire than for the QLQ-C30 questionnaire (9 and 5%, respectively, $P<0.001$). 36

Table 3
Descriptive statistics and psychometric properties of the French FACIT

Scale	No. of items	Missing data (%)	Score mean[a] (S.D.)	Standardised Score Mean[a] (S.D.)	Cronbach α coefficient
Descriptive statistics					
Physical WB	7	9	70 (19.9)	63 (14.5)	0.82
Social/Family WB	7	13	83 (13.6)	64 (14.1)	0.79
Emotional WB	5	7	73 (19.4)	60 (17.5)	0.73
Functional WB	7	7	53 (22.2)	52 (15.4)	0.87
Overall	26				

Validation[a] Scale	Internal consistency Success rate[c]	Discriminant validity Success Rate[d]
Physical WB	86	62 (95)
Social/Family WB	100	76 (100)
Emotional WB	80[e]	53 (100)
Functional WB	100	67 (100)
Overall	92	65 (99)

S.D., standard deviation; WB, Well-Being; values in brackets are success meaning correlation $\geqslant 1$ standard error.

[a] Analysis on 61 computable cases. Each sub-scale score was calculated according to two procedures: (i) the algebraic mean of the raw scores of the items completed transformed to a 0–100 score after linear transformation (the higher the score the better the individual's health); (ii) the algebraic mean of the standardised scores derived from the raw scores based on score conversion tables provided by Cella.

[c] Success: items-scale correlation greater than or equal to 0.40 (corrected).

[d] Significant success means correlation $\geqslant 2$ standard errors.

[e] One item with low item-internal consistency: GE2 (how I am coping with my illness).

Table 4
Results

	FACIT	QLQ-C30	*P* value
Preference			NS
One	13 (19%)	13 (19%)	
One or the other	37 (54%)		
Neither of the two	2		
No response	3		
Acceptability criteria			
Inadequately-worded	20 pts (29%)	13 pts (19%)	NS
Intrusive	16 pts (24%)	2 pts (3%)	<0.001
Unanswered	9% of the items	5% of the items	<0.001

NS, non-significant; pts, patients.

patients did not complete the sex life item in the FACIT questionnaire. If these missing answers are excluded, the overall rate of unanswered items decreases to 7%, but remains significantly higher ($P=0.01$) for the FACIT questionnaire. FACIT items were more often considered inadequately-worded (29 and 19% of the patients for FACIT and QLQ-C30, respectively), although the difference was non-significant. FACIT items were more often perceived as intrusive than the QLQ-C30 items (24 and 3%, respectively, $P<0.001$). The items most often mentioned for the FACIT questionnaire concerned sex life (nine times), worrying about dying (four times) and satisfaction with quality of life (four times), while those mentioned for the QLQ-C30 concerned the physical role (once) or social role (once). The 'difficult' items, as defined above, are presented in Table 5. There were 14 and five 'difficult' items for the FACIT and QLQ-C30 questionnaires, respectively ($P=0.003$). All the 'difficult' items in the FACIT questionnaire were similarly distributed across the four domains (Physical, Social/Family, Emotional and Functional Well-Being). The item 'sex life' (GS7) was most often 'difficult' (i.e. not completed or considered intrusive or inadequately worded) (38 patients)]. The 'difficult' items in the QLQ-C30, concerned Physical Functioning and Role Functioning, Social Functioning and Global Quality of Life.

3.5. Qualitative analysis of the patients comments

Qualitative data are important for deep insights and statistics are generally not included in qualitative analysis. Three major themes appeared from the content analysis: (1) the complementary aspects of the two scales (2) the lack of precision of certain items (3) omissions identified by the patients in the two scales.

(1) The two questionnaires were felt to be complementary in form and in content. The following comments were recorded: "the two questionnaires are complementary" ; "the QLQ-C3O is all right, but the FACIT would make it more complete". With regard to the form, QLQ-C30 items were judged to be "very precise questions", while "questions in the FACIT are more confusing". However, 1 patient did prefer the item wording in the FACIT questionnaire because it expressed "greater personal involvement". Patients thought the FACIT questionnaire was "better organised" than the QLQ-C30 and the "classification according to themes" was considered "more logical".

Table 5
'Difficult' items observed for the FACIT and QLQ-C30 questionnaires

Difficult items	Corresponding domains	No. of patients concerned	Occurrences		
sorted according to decreasing frequency			Unanswered	Intrusive	Inadequately worded
FACIT	Well-Being				
GS7: sex life	Family and Social	38	36	9	7
GP3: trouble meeting the needs of my family	Physical	12	8	2	4
GF7: content with the quality of my life	Functional	12	5	4	6
GE2: how I am coping with my illness	Emotional	11	5	1	5
GP5: side-effects of treatment	Physical	10	8	0	2
GP4: I have pain	Physical	9	7	0	2
GS6: close to my partner	Familial and Social	8	6	2	0
GE3: losing hope in the fight against my illness	Emotional	8	5	1	2
GF1: able to work	Functional	8	5	0	3
GE5: worry about dying	Emotional	7	4	4	3
GF4: accepted my illness	Functional	7	3	1	3
GP7: forced to spend time in bed	Physical	7	7	0	0
GF2: work (including at home) is fulfilling	Functional	7	7	0	2
GS3: support from my friends	Family and Social	7	6	1	0
QLQ-C30	Functional Scales				
Q6: limited work or daily activities?	Role Functioning	12	7	1	5
Q7: limited hobbies/leisure time activities?	Role Functioning	10	6	1	3
Q2: trouble taking a long walk?	Physical Functioning	9	7	0	3
Q27: social activities?	Social Functioning	8	5	1	3
Q30: overall health	Global QOL	8	3	0	5

With regard to content, patients felt that the QLQ-C30 "allows an accurate description of the patient's physical abilities and limitations", while "FACIT is more related to my quality of life with my family".

(2) Critical remarks were levelled at items in both measures. With regard to the QLQ-C30: "there is no time-frame" for items concerning Physical Functioning, which might explain why some patients failed to reply to these questions. Items 6 and 7 (limitations in daily activities) were "considered bungled". Another patient said: "You are asking me a question about my professional activities, but it is two months since I had to give up all my activities as I am either in hospital or convalescing. So, what can I possibly reply to these questions?" With regard to the FACIT questionnaire, remarks mainly concerned three items. The satisfaction/sex life item (GS7) was considered annoying and it, and some of the following items sometimes elicited "irritating" reactions : "ridiculous question" another patient wrote: "As I am weak in general, I have neither the energy, nor the desire [...], but I still have feelings". Item GE5 states: "I worry about dying". One patient crossed it out and replaced it by "I don't want to die!!!" Another replied "not at all" circled twice. Item GF7: "I am content with the quality of my life right now" was not easily accepted by the patients: "Given my illness, I can't see how I could be [content]".

(3) Several patients suggested that questions be added in two dimensions in order to improve the scale: the experience of treatment (quality of medical and nursing care) and their morale (psychological well-being).

4. Discussion

The aim of the study was to assist clinicians in their choice of a QOL measure that would be valuable for use in cancer clinical trials with patients with a CUP. We examined the two most commonly used measures, available in the French language, in 68 cancer patients.

The patients completed in a random order the two QOL questionnaires: QLQ-C30 and FACIT. The same percentage of patients (19%) preferred the QLQ-C30 and the FACIT. The choice of questionnaire was therefore based on acceptability criteria. As the FACIT had the highest number of missing data (9% versus 5%, $P<0.001$) and scored the highest rates for items considered inadequately worded (29% versus 19%, non-significant) or intrusive (24% versus 3%, $P<0.001$), we believe in our study the QLQ-C30 to be the most acceptable questionnaire. The concept 'difficult items' has helped us to summarise the acceptability criteria: 14 items in the FACIT questionnaire were 'difficult' for more than 10% of the patients, while there were five only in the QLQ-C30 ($P=0.003$).

Surprisingly, only 38% of patients expressed a preference for one of the two measures, and 54% were ready to accept either of the two. Did the latter not understand what was expected of them? Although the patient information letter was entitled 'Quality of Life Evaluation study', it is possible there was a certain ambiguity between quality of life evaluation and state of health which might explain these findings. Did they simply feel that the content of the two questionnaires was different and that there were no grounds for choosing one rather than the other (as did the clinicians)? The fact that some of them felt the questionnaires were complementary favoured the latter assumption. Whatever the reason, the choice of the scale could not be based on patients' preference, and the final decision was based on the acceptability criteria [15].

No refusals to complete the QOL measures were observed, probably because patients with a CUP are very anxious and ready to follow the recommendations of the clinicians. Moreover, the clinicians involved in this study were very motivated, so they encouraged the patients to fill in the QOL questionnaires. The percentage of unanswered items was significantly higher for the FACIT (9%) than for the QLQ-C30 (5%). Conroy [9] in 310 patients with breast cancer, colorectal cancer and head and neck cancer also observed a higher percentage of unanswered items, 5 and 1.8%, for FACIT and QLQ-C30, respectively. With regard to the QLQ-C30 [4,16], the EORTC and Medical Research council (MRC) experience suggests that the percentage of unanswered questions varies between 0.5% and 2.0 in the returned questionnaires. Fairclough [17] reported a 1.7% rate of missing data in a series of 465 American patients who were administered the FACT-G. In the study of a multilingual translation of the FACT-G into six European languages, Bonomi and Cella [11] reported missing data rates ranging from 1 to 5% (France) estimated on small samples (approximately 16 patients for each language), and thought to be attributable to cultural factors, especially sexuality (GS7) a taboo subject in some European countries, and how one is coping with one's illness (GE2). The information given by the 'debriefing' items might shed some light on our high rate of missing data. Here again, the percentage of patients for whom items were classified as 'difficult' was greater for the FACIT than for the QLQ-C30, both for inadequately-worded items, and for intrusive items The sexual item in our study (GS7) had a high percentage of missing data (53%) and was the item most frequently mentioned as intrusive and inadequately-worded. Patients' general comments suggested this implied a notion of 'sexual performance' rather than the idea of one's sex life on the whole which they felt preferable. Apart from this, it is also probably related to the overall poor performance status and poor prognosis (median survival: 8 months) of this population of patients. "Satisfaction with sex life" (GS7), "Satisfaction with one's quality of life" (GF7) and "Satisfaction with how one is coping with one's illness" (GE2) were considered the most inadequately-worded items. The word 'proud' was used in the FACT-G version 2. Bonomi [11] reported that this word conveyed the idea of vanity, and used the word 'satisfied' in the following version. Nevertheless, this word still suggests an idea of challenge that 'satisfait' does not express to the same degree in French. The fact that this item is unsatisfactory may explain the poor item-internal consistency observed.

Another important cultural difference concerns the information the patient receives about their illness. The diagnosis of cancer is unveiled during the course of the illness, taking into account the patient's ability or desire to be fully aware of his/her condition. Reading "I worry about dying" unleashed thoughts such as: "I didn't realise that my illness was so serious", provoking an emotional upheaval. Management by a psychologist would have been advisable in several study patients. Furthermore, we felt that the formulation of FACIT items was perceived as too direct: a statement using 'I' directly involves the patient in the concept conveyed, whereas if the items were formulated as a question, it enables the patient to distance himself from the item, especially as 'vous' can be used which can also refer to someone else in French and not 'tu', on an equal footing with 'je' (I) which is applicable to a single individual, the one reading the questionnaire. The problems concerning the items mentioned in this paragraph are not specific to French culture; they have also been observed in Germany and in Japan [18]. Concerning the QLQ-C30, 1 patient noted "there is no time-frame for the first five items", which could explain failure to reply to these questions. Aaranson [4] reported that approximately 10% of the patients considered one or more items to be confusing, i.e. lower than in our study, but the rate of patients reporting intrusive items was low and similar to ours: 3%. Nevertheless, explaining the aim of the study to the patients and asking them questions on what they thought about the items may have motivated them to reply.

Our conclusion was that in future studies the QLQ-C30 has advantages over the FACIT measure. However, it should be emphasised that these results precisely applied for a sample of French patients with a very poor prognosis cancer (CUP), who were administrated the FACIT questionnaire modified for a few items that were not suitable for these French patients.

Patients' comments concerning the complementary aspects of the two questionnaires are clear and point to a new issue. Are the unfavourable indicators in the FACIT due to cultural factors, to the wording of the items? If the scales are truly complementary, should we not design another scale combining the medical and physical orientation of the QLQ-C30 and the existential approach of the FACIT to be in line with patients' wishes? These questions remain unanswered.

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