ELSEVIER

European Journal of Cancer 40 (2004) 2243–2252

European Journal of Cancer

www.ejconline.com

French version of FACT-G: Validation and comparison with other cancer-specific instruments

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Received 28 January 2004; received in revised form 17 May 2004; accepted 15 June 2004
Available online 6 August 2004

Abstract

The aim of this study was to assess the validity of the French version of the Functional Assessment of Cancer Therapy – General (FACT-G), and to compare its psychometric properties with those of two other cancer-specific quality of life questionnaires, European Organisation for Research and Treatment of Cancer Quality of Life – Core 30 (EORTC QLQ-C30) and Functional Living Index – Cancer (FLIC). Two hundred and twenty three patients with breast or colorectal cancer completed the FACT-G questionnaire in French followed by (in random order) the QLQ-C30 and FLIC. An additional 87 patients with head and neck (H&N) cancer completed the FACT-H&N followed by the QLQ-C30 and H&N-Besançon. The French version of FACT-G was internally consistent, and its reproducibility was excellent. FACT-G Physical Well-Being and global scores correlated with all QLQ-C30 subscales. There was evidence of discriminant validity. Compared with the other tools, FACT-G included a statistically significantly higher proportion of items patients considered to be confusing or upsetting. Patients with breast or colorectal cancer expressed a preference for QLQ-C30. Use of the specific H&N additional items increased the responsiveness to change of FACT-G. The French version of FACT-G is valid and has psychometric properties similar to those of FLIC and QLQ-C30.

Keywords: Validation; Quality of life; FACT-G; EORTC QLQ-C30; FLIC; Breast cancer; Colorectal cancer; Head and neck cancer

1. Introduction

It is increasingly common for oncology trials to include quality of life (QoL) as an end-point. However, QoL data are of little value unless they have been obtained using a validated questionnaire of proven applicability in the context concerned.

Three of the most widely used cancer-specific QoL tools are: the Functional Living Index – Cancer (FLIC) [1,2]; the European Organisation for Research and Treatment of Cancer (EORTC) QLQ-C30 [3,4]; and the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire [5]. The most frequently used questionnaire is the FACT-G in the United States of America and the EORTC QLQ-C30 in Europe and Canada [6]. Version 3 of FACT-G has been pre-tested in 16 French patients [7], but its cross-cultural validity has yet to be fully investigated.

The aims of the present study were to determine the validity of the French version of FACT-G, to compare its psychometric properties with those of QLQ-C30 and FLIC, and to investigate patient preferences. In addition, two head and neck (H&N)-specific questionnaires–FACT-H&N [8] and the Besançon H&N questionnaire (H&N-B) [9] – were assessed for responsiveness to change.

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doi:10.1016/j.ejca.2004.06.010

2. Patients and methods

2.1. Sample and design

The study population consisted of patients with breast, colorectal or H&N cancer. Inclusion criteria were a Karnofsky index above 60, age below 80 years, ability to understand written and spoken French, and provision of written consent. Breast cancer patients were receiving adjuvant chemotherapy, colorectal cancer patients either adjuvant or palliative chemotherapy, and H&N cancer patients a radiotherapy dose of 50 Gray or more.

Patients with breast or colorectal cancer were surveyed at home on Day 8 of chemotherapy. They completed FACT-G version 3 followed by QLQ-C30 version 3 and FLIC in randomised order. Main features of these 3 instruments are depicted in Table 1. In order to assess test–retest reliability, breast cancer patients completed the same questionnaires during two consecutive courses (21-day interval) of adjuvant chemotherapy. Forms were returned by mail.

A research nurse gave to H&N cancer patients the FACT-H&N (FACT-G + 11 H&N-specific questions) followed by QLQ-C30 and H&N-B in a randomised order. To enable the responsiveness to change to be determined, questionnaires were completed in hospital during both the first and the last week of radiotherapy.

To assess acceptability, all patients completed a debriefing questionnaire covering how long each questionnaire took to complete, and whether any items were confusing or upsetting. They were also asked the six questions listed in Fig. 1. They were finally requested: 'You answered 3 questionnaires. Which one did you prefer (FLIC, EORTC, FACT)'?

2.2. Analyses

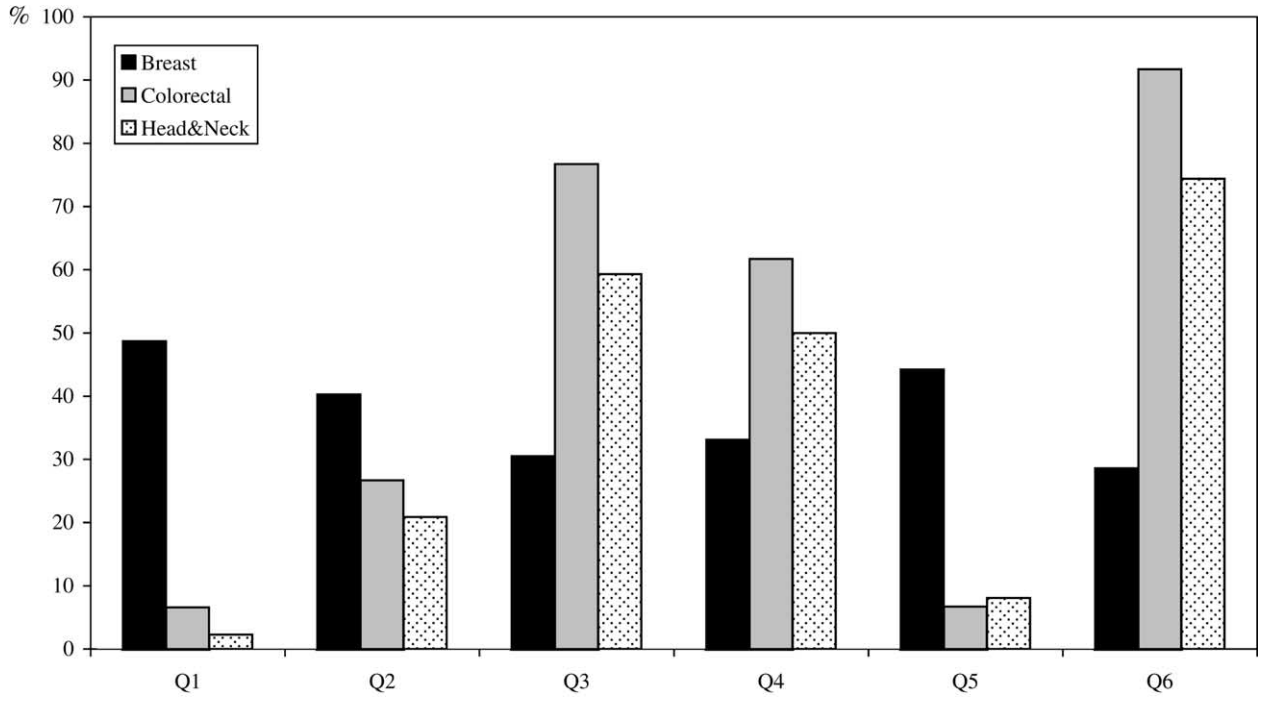
Completed questionnaires were scored according to the developers' instructions [1,8–11]. All results, other than reproducibility and responsiveness to change, relate only to the first administration. Acceptability was determined by evaluating responses to the questions in Fig. 1, the time required to complete the questionnaires, and the percentages of missing values, and of confusing or upsetting items. Paired series were compared using Mac Nemar's exact test and *t*-tests, and data on patient preference using the Chi-square test. We did not compare EORTC QLQ-C30 and FACT-G in H&N cancer patients because H&N-specific questions were not separated from FACT-G in the FACT-H&N questionnaire.

Internal consistency was evaluated using Cronbach's α coefficient [12], construct validity using factor analysis, and convergent validity using Spearman's rank correlation coefficient [13]. Discriminant validity was estimated in terms of the correlation between scores and relevant patient characteristics using an analysis of variance (ANOVA). The reproducibility of scores in patients with stable disease was assessed using the intraclass correlation coefficient (ICC). Responsiveness to

Table 1
Important features of the instruments

	EORTC QLQ-C30 Version 3.0	FACT-G Version 3	FLIC
No. of items	30	34	22
Global score	No	Yes	Yes
Sub-scores	15	5	No
Subscales (No. of items)	Physical functioning (5) Social functioning (2) Emotional functioning (4) Cognitive functioning (2) Role functioning (2) Fatigue (3) Pain (2) Nausea and vomiting (2) Global health status/QoL (2)	Physical Well-Being (7) Social/Family Well-Being (7) Emotional Well-Being (6) Relation With Doctor (2) Functional Well-Being (7)	Hardship (3) Sociability (2) Emotional (4) Confidence in treatment (1) Role (4) Pain (2) Nausea (2) Current health (3)
Negative wording	28/30	14/29	14/22
Syntax structure	Questions	Statements	Mainly questions
Item's content	Every day situation, symptoms	Existential problems, satisfaction	Existential problems and symptoms
Item's order	Mixed	Modular	Mixed
Time scale	Past week	Past seven days	Past month, past two weeks, current status

EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life – Core 30.
FACT-G, Functional Assessment of Cancer Therapy – General.
FLIC, Functional Living Index – Cancer.
QoL, quality of life.



Q1 : This questionnaires take too long to fill in
Q2 : It is difficult to fill in the two last questionnaires because the questions are similar to those in the first one
Q3 : Would you agree to fill in these questionnaires several times during and after your treatment ?
Q4 : Does filling in the different questionnaires allow you to express yourself more freely or more easily ?
Q5 : Were some of the questions upsetting ?
O6 : Do you think that these questionnaires can help your physicians understand your quality of life ?

Fig. 1. Responses to debriefing questions (percentage of positive answers).

change was analysed using variations in scores and the standardised response mean [14,15]. Pain and swallowing were assessed according to World Health Organisation (WHO) toxicity criteria. Patients who had an increase in toxicity with grade > 1 during radiotherapy were included in the worsening group (Group 2). Patients with grade 1 as the maximum toxicity were considered as unchanged (Group 1).

The study hypothesis was that when the FACT-G French version is administered to a French population, its psychometric characteristics are equivalent to those of the original English version. A two-sided alpha level of 0.01 allowed for multiple comparisons to be made. Data were analysed using Statistical Analysis System software (version 8.2).

3. Results

Between September 1996 and December 1997, 310 patients were enrolled in to the study. Sociodemographic characteristics of the study population were as shown in Table 2. Of 556 questionnaires analysed, 310 were from the first administration, and 246 from the second administration (four of 250 of the latter were missing).

3.1. Acceptability and preferences

Average completion times were as shown in Table 3. None of the differences reached statistical significance. As also shown in Table 3, compared with the other instruments, FACT-G included significantly higher proportions of items considered confusing or upsetting. The FACT-G items that were most frequently rated as confusing were items 13 ('Family communication about my illness is poor') and 15 ('I am satisfied with my sex life'). These two items were considered as confusing for 5.5% and 5.2% of the patients, respectively. Item 15 was considered as upsetting by 7.7% of the patients. Significantly fewer items were missing from FLIC than from the other instruments. Thirty-two percent of the patients did not answer FACT-G item 15 and 17% FACT-G item 14 ['I feel close to my partner or main support']. No correlation was seen between the missing answer of item 15 on sexual life and marital status. Items 12, 21 and 29 of FACT-G were not filled by 9% of the patients. Item 16 of H&N-B ['Have you had trouble with eating in front of other people ?'] and item 38 of FACT-H&N ['My voice has its usual quality and strength'] were not answered by 9% and 12% of the patients, respectively. All the other items had less than 7.5% of missing data. A

Table 2
Sociodemographic variables and clinical characteristics

Variable	All patients	Breast cancer	Colorectal cancer	Head and neck cancer
	($N = 310$)	($N = 163$)	($N = 60$)	($N = 87$)
	No. (%)	No. (%)	No. (%)	No. (%)
Age in years: mean (SD)	53 (11)	48 (9)	60 (12)	58 (9)
Gender: No. (%)				
Male	114 (37)	0 (0)	34 (57)	80 (92)
Female	196 (63)	163 (100)	26 (43)	7 (8)
Aim of treatment: No. (%)				
Adjuvant	270 (87)	163 (100)	20 (33)	87 (100)
Palliative	40 (13)	0 (0)	40 (67)	0 (0)
Marital Status: No. (%)				
Single	35 (11)	19 (12)	6 (10)	10 (12)
Married	220 (71)	121 (74)	43 (72)	56 (64)
Widowed	23 (7)	10 (6)	8 (13)	5 (6)
Divorced	29 (9)	12 (7)	3 (5)	14 (16)

SD, standard deviation.

trend for women to express more negative views than men about the usefulness of the questionnaires failed to reach statistical significance ($P < 0.03$).

Only 58.1% of H&N patients expressed a preference (23.3% for FACT-H&N, 15.1% for EORTC QLQ-C30, 19.8% for H&N-B). Preference of patients with other primary tumours was as shown in Fig. 2. Distribution preference (no preference – FACT – EORTC – FLIC) differs from uniform distribution for colorectal ($P = 0.001$), breast cancer ($P = 0.048$) patients and for

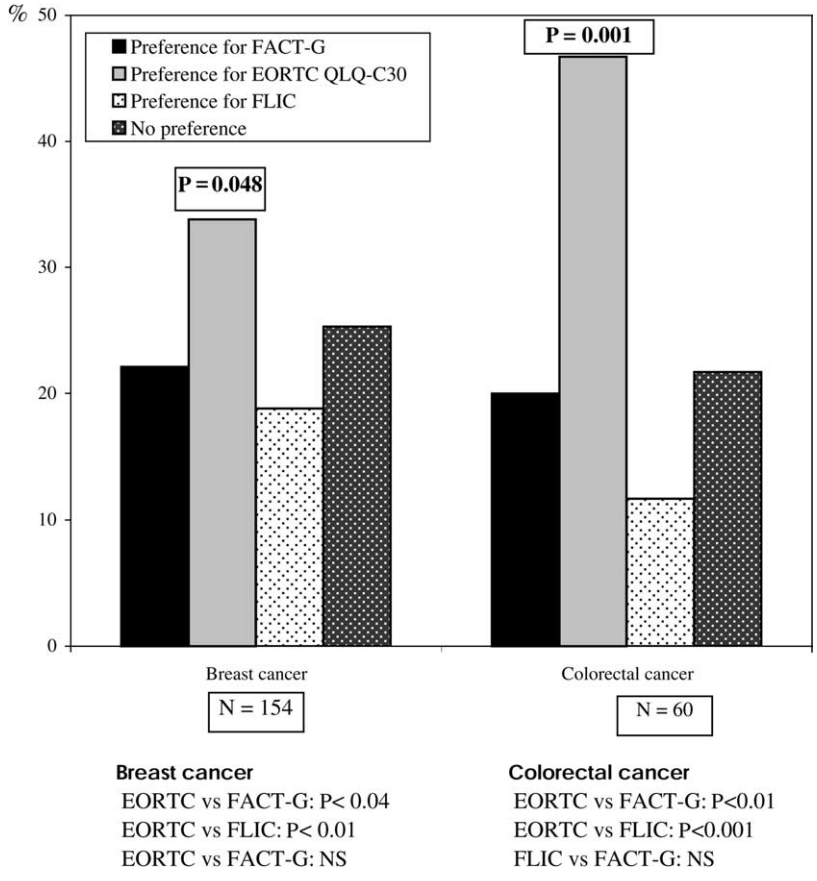


Fig. 2. Patients preferences.

Table 3
Results to debriefing questionnaires ($N = 310$)

Time to completion (min)				% Items		
Questionnaire	Breast	Colorectal	H&N	Confusing	Upsetting	Missing
FACT-G	7.9′	10.2′	11.6′[d]	1.38[a]	0.64[ac]	5.23[ac]
QLQ-C30	6.6′	7.9′	7.9′	0.36[ab]	0.03[a]	1.76[ab]
FLIC	7.4′	8.4′	–	1.01[b]	0.17[c]	0.30[bc]

[a] FACT-G vs QLQ-C30: $P < 0.00001$.
[b] QLQ-C30 vs FLIC: $P < 0.000001$.
[c] FACT-G vs FLIC: $P < 0.0001$.
[d] FACT-H&N.

both cancer localisations' patients ($P < 0.001$). When mixing both sites, preferences differ significantly when comparing EORTC to FACT-G ($P = 0.002$) and EORTC to FLIC ($P < 0.001$), but not FLIC to FACT-G. No correlations between sociodemographic characteristics and patients' preferences were observed.

3.2. Psychometric properties

3.2.1. Reliability

3.2.1.1. Internal consistency. Cronbach's α for FACT-G scales are presented in Table 4 together with Cronbach's α coefficients of the original English instruments. Only one FACT-G domain ('Relationship With Doctor') exhibited a ceiling effect, with a 31% perfect score. QLQ-C30 role, cognitive and social functioning domains exhibited more than 25% perfect scores (Table 4). Floor effects were low throughout, other than for QLQ-C30 role functioning (11%).

3.2.1.2. Test–retest reliability. The median time between two consecutive questionnaire administrations was 23 days (range: 18–34 days). The three questionnaires exhibited good reproducibility, with FACT-G being slightly superior (ICC values: 0.79 to 0.88 for FACT-G; 0.70 to 0.82 for QLQ-C30; and 0.82 for FLIC).

3.3. Validity

3.3.1. Construct validity

Factor-analysis revealed five significant factors that accounted for 57% of the total variance. Table 5 lists the FACT-G item loadings. Items 13 and 21 had a greater loading in another subscale than the original one.

Table 4
Internal consistency, Cronbach's α and ceiling-floor effect for the three questionnaires ($N = 310$)

	Number of items (range of scores)	Scores		Ceiling effect (%)	Floor effect (%)	α	α*
		Mean	(SD)				
FACT-G Subscale							
Physical Well-Being	7 (0–28)	20.45	(5.93)	8.50	0.33	0.87	*0.82*
Functional Well-Being	7 (0–28)	15.30	(5.56)	1.63	1.31	0.84	*0.80*
Social/Family Well-Being	7 (0–28)	20.65	(4.34)	0.98	0.00	**0.66**	***0.69***
Emotional Well-Being	5 (0–20)	14.51	(3.76)	4.90	0.00	**0.68**	*0.74*
Relationship With Doctor	2 (0–8)	6.40	(1.46)	**30.72**	0.65	0.84	***0.65***
Global	28 (0–112)	77.19	(14.71)	0.00	0.00	0.88	*0.89*
FACT-H&N subscale	11 (0–44)	15.71	(5.64)	0.00	0.00	**0.52**	***0.63***
FLIC	22 (22–154)	101.49	(19.34)	0.00	0.00	0.95	*0.90*
EORTC QLQ-C30							
Physical	5 (0–100)	78.5	(18.60)	19.28	0.00	0.73	*0.71*
Role	2 (0–100)	62.76	(33.49)	**28.76**	10.78	0.90	***0.52***
Emotional	4 (0–100)	67.91	(26.21)	14.71	1.96	0.86	*0.80*
Cognitive	2 (0–100)	76.04	(24.80)	**33.99**	1.31	**0.60**	*0.73*
Social	2 (0–100)	68.42	(29.82)	**32.68**	3.92	0.77	*0.77*
Global QoL	2 (0–100)	58.11	(22.14)	5.55	0.98	0.92	*0.89*

α → Cronbach's alpha coefficient.
α* → Cronbach's alpha coefficient original version of FACT-G by Cella and colleagues [4], of FACT-H&N by List and colleagues [8], of the French version of FLIC by Mercier and colleagues [8], and of QLQ-C30 by Aaronson and colleagues [9].

Table 5
Factor analysis (varimax rotation) of FACT-G: percentage of variance and item loadings greater than 0.30

Subscale item	1	2	3	4	5
Physical Well-Being (PWB)					
1. I have a lack of energy	0.73	0.30			
2. I have nausea	0.70				
3. I have trouble meeting the needs of my family	0.69	0.31			
4. I have pain	0.49			0.32	
5. I am bothered by side-effects of treatment	0.78				
6. In general I feel sick	0.74				
7. I am forced to spend time in bed	0.77				
Social/Family Well-Being (SWB)					
9. I feel distant from my friends	0.40		0.25	0.30	
10. I get emotional support from my family			0.89		
11. I get support from my friends and neighbours			0.89		
12. My family has accepted my illness			0.77		
13. Family communication about my illness is poor			**−0.17**		
14. I feel close to my partner (or main support)			0.59		
15. I am satisfied with my sex life		0.32	0.40		
Relationship With Doctor (RWD)					
17. I have confidence in my doctors					0.87
18. My doctor is available to answer my questions					0.88
Emotional Well-Being (EWB)					
20. I feel sad	0.54			0.53	
21. I am proud of how I'm coping with my illness		**0.46**		0.25	
22. I am losing hope in the fight against my illness				0.73	
23. I feel nervous	0.34			0.57	
24. I worry about dying				0.74	
Functional Well-Being (FWB)					
27. I am able to work (including housework)	0.35	0.71			
28. My work (including housework) is fulfilling	0.40	0.70			
29. I am able to enjoy life		0.72			
30. I have accepted my illness		0.44		0.51	
31. I am sleeping well		0.42		0.37	
32. I am enjoying my usual leisure pursuits		0.66			
33. I am content with the quality of life right now	0.33	0.68			
Percentage of variance: all patients	27%	12%	7%	6%	5%
Cella and colleagues [4]	22%	9%	9%	6%	5%

Item 13 did not load in any factor.

3.3.2. Convergent validity

As Table 6 shows, correlations between FACT-G and QLQ-C30 were, in general, substantial when scales related to the same QoL domain, and low when they related to different domains. A high correlation was observed between FACT-G Physical Well-Being and all the function scales of QLQ-C30. The social domains of FACT-G and QLQ-C30 were poorly correlated, but the emotional subscales were highly correlated. The FACT-G global score was correlated with all QLQ-C30 domains. FACT-G Physical Well-Being correlated with FLIC domains (Table 6) other than sociability and confidence in treatment. Correlation between the FACT-G 'Relationship With Doctor' and FLIC 'confidence in treatment' domains was, at 0.36, greater than for any other FLIC scale. FLIC and FACT-G emotional domains and global scores were highly correlated. FACT-G Functional Well-Being was correlated with all EORTC functional scales and with some FLIC domains (principally current health, emotional, and role) and global score.

3.3.2.1. Discriminant validity. Differences between means according to gender, marital status, diagnosis and Karnofsky index are illustrated in Table 7. QoL scores were lower among patients with breast cancer, and those with H&N cancers who were living alone. Education, housing, age and employment status had no statistically significant effects. Tumour site was associated with significant differences in Physical and Emotional Well-Being, and in global FACT-G score ($P < 0.0001$).

3.3.2.2. Responsiveness to change in H&N patients. The median time between the beginning and the completion of radiotherapy was 38 days (range: 26–54 days). The

Table 6
Spearman scale correlations between FACT-G, EORTC QLQ-C30 and FLIC *(number of patients)*

FACT-G							
		PWB	SWB	RWD	EWB	FWB	Global
QLQ-C30	Physical	**0.54** *(294)*	0.11 *(288)*	0.13 *(290)*	**0.40** *(293)*	**0.51** *(293)*	***0.55*** *(274)*
	Role	**0.71** *(290)*	0.01 *(284)*	0.17 *(286)*	0.35 *(289)*	**0.50** *(290)*	**0.57** *(272)*
	Emotional	**0.58** *(293)*	0.13 *(287)*	0.09 *(289)*	**0.71** *(292)*	**0.52** *(293)*	**0.65** *(274)*
	Cognitive	**0.58** *(293)*	0.13 *(287)*	0.12 *(289)*	**0.48** *(292)*	**0.48** *(293)*	**0.58** *(274)*
	Social	**0.69** *(290)*	0.08 *(285)*	0.13 *(286)*	0.39 *(289)*	**0.52** *(290)*	**0.60** *(272)*
	Global QoL	***0.70*** *(291)*	*0.09 (285)*	*0.24 (287)*	***0.47*** *(290)*	***0.59*** *(291)*	***0.66*** *(272)*
FLIC (*)	Current health	**0.58** *(203)*	0.22 *(201)*	0.13 *(203)*	**0.42** *(203)*	**0.58** *(204)*	**0.61** *(195)*
	Sociability	0.16 *(203)*	0.25 *(201)*	0.14 *(203)*	0.23 *(203)*	0.29 *(204)*	0.28 *(195)*
	Confidence in treatment	0.29 *(203)*	0.29 *(201)*	0.36 *(203)*	**0.48** *(203)*	0.37 *(204)*	**0.47** *(195)*
	Emotional	**0.56** *(203)*	0.30 *(201)*	0.11 *(203)*	**0.75** *(203)*	**0.60** *(204)*	**0.72** *(195)*
	Hardship	**0.58** *(203)*	0.15 *(201)*	0.11 *(203)*	**0.44** *(203)*	**0.49** *(204)*	**0.58** *(195)*
	Role	**0.61** *(203)*	0.28 *(201)*	0.13 *(203)*	**0.47** *(203)*	**0.68** *(204)*	**0.70** *(195)*
	Global	**0.77** *(203)*	0.32 *(201)*	0.19 *(203)*	**0.66** *(203)*	**0.76** *(204)*	**0.84** *(195)*

(*), Domains of FLIC defined according to King and colleagues [16].
EWB, Emotional Well-Being, PWB, Physical Well-Being.
SWB, Social/Family Well-Being.
FWB, Functional Well-Being.
RWD, Relationship With Doctor.

Table 7
Values of FACT-G scores according to patient characteristics

Characteristics (*N*)	Global score		PWB score		SWB score		EWB score		FWB score	
	m (SD)	*P* value	m (SD)	*P* value	m (SD)	*P* value	m (SD)	*P* value	m (SD)	*P* value
Gender		**0.0007**		**<0.0001**		**0.32**		**<0.0001**		**0.52**
Male (114)	80.9 (12.1)		23.2 (4.4)		20.3 (4.2)		15.6 (3.2)		15.6 (5.5)	
Female (196)	75.1 (15.6)		18.8 (6.0)		20.8 (4.5)		13.8 (3.9)		15.1 (5.6)	
Marital Status		**0.043**		**0.61**		**0.07**		**0.012**		**0.008**
Single (28)	70.6 (12.2)		19.7 (5.9)		19 (4.8)		13.1 (3.6)		12.6 (5.2)	
Married (197)	77.8 (14.6)		20.4 (6.0)		20.9 (4.3)		14.5 (3.8)		15.4 (5.6)	
Widowed/ Divorced (44)	78.8 (15.8)		21.0 (5.6)		20.5 (4.3)		15.6 (3.5)		16.2 (5.2)	
Primary tumour		**<0.0001**		**<0.0001**		**0.79**		**<0.0001**		**0.14**
Breast (144)	73.8 (15.6)		18.2 (6.0)		20.7 (4.6)		13.5 (3.9)		14.6 (5.5)	
Colorectal (54)	79.0 (14.1)		20.9 (5.0)		20.8 (3.3)		15.0 (3.5)		15.8 (6.0)	
Head and Neck (74)	82.7 (11.3)		24.2 (3.8)		20.4 (4.5)		16.1 (3.1)		16.0 (5.3)	
Karnofsky index		**0.0035**		**0.0015**		**0.02**		**0.006**		**0.0001**
100-90 (245)	78.9 (14.4)		21.0 (5.8)		21 (4.4)		14.8 (3.6)		15.9 (5.5)	
$\leqslant$ 80 (57)	70.3 (14.3)		18.3 (5.8)		19.4 (4.0)		13.3 (3.9)		12.7 (5.2)	

m, mean.
PWB, Physical Well-Being.
SWB, Social/Family Well-Being.
EWB, Emotional Well-Being.
FWB, Functional Well-Being.

most responsive subscales were FACT-G Physical and Functional Well-Being and QLQ-C30 global QoL, with variations ranging from 11% to 14% (Table 8). However, larger variations were observed in the H&N-specific questionnaires, reaching 22.4% and 36% for FACT-H&N and H&N-B, respectively. Results were similar using the standardised response mean. Analysis of toxicity data confirmed the sensitivity of FACT-G Physical and Social/Family Well-Being to changes in pain and swallowing (Table 9).

4. Discussion

The present findings show that the French versions of FACT-G, FLIC and QLQ-C30 reached reasonable

Table 8
Responsiveness in head and neck patients: change of scale scores between the end and the beginning of radiotherapy

N = 79	Md	*P* value (Wilcoxon)	*V* (%)	SRM[a]
FACT subscale				
Physical Well-Being	−3.38	**0.0001**	**−14**	**−0.60**
Social/Family Well-Being	−0.08	0.95	−0.4	−0.02
Relationship With Doctor	*0.07*	0.82	*1.05*	0.03
Emotional Well-Being	−0.51	0.21	−3.14	−0.15
Functional Well-Being	−1.81	**0.003**	**−11.00**	**−0.32**
Global	−3.95	**0.008**	**− 4.70**[b]	**−0.30**
EORTC global QoL	*−9.20*	**0.0006**	***−13.3***[b]	**−0.40**
Physical functioning	−3.3	0.4024	−4.0	−0.12
Role functioning	−9.6	0.0079	−11.6	−0.18
Emotional functioning	−4.8	0.0741	−6.1	−0.21
Cognitive functioning	−5.9	0.0063	−6.7	−0.25
Social functioning	−7.2	0.0005	−8.9	−0.33
FACT H&N	−3.59	**0.0001**	**−22.4**[b]	**−0.61**
H&N-B	*11.3*	**0.0001**	***36.0***[c]	**1.08**

Md, mean differences in scores between two assessments.
V%, relative variation of scores (Md/initial score × 100).
SRM, standardised response mean (Md divided by the standard deviation of the score difference).
H&N-B, Head and Neck Besançon questionnaire.
[a] A higher standardised response means (SRM) indicate greater sensitivity to change, with SRM of 0.2, 0.5, and 0.8 or above representing small, moderate, and large changes, respectively.
[b] A higher score in EORTC global QoL, FACT-G and FACT-H&N indicates a better QoL.
[c] A decrease in H&N-B indicates a better QoL.

Table 9
Responsiveness of FACT, FACT H&N EORTC and H&N-B questionnaires according to toxicities during radiotherapy

N = 79	Md Group 1	Md Group 2	*P* value
FACT subscale			
Physical Well-Being	−2.41	−4.56	**0.04**
Social/Family Well-Being	0.88	−1.37	**0.045**
Relationship With Doctor	0.12	0.06	0.84
Emotional Well-Being	−0.11	−1.03	0.20
Functional Well-Being	−1	−2.62	0.13
Global	−0.92	−6.66	**0.02**
EORTC global QoL	−7.14	−12.5	0.26
Physical functioning	1.43	−9.33	**0.02**
Role functioning	−5.98	−14.29	0.27
Emotional functioning	−5.05	−4.66	0.93
Cognitive functioning	−4.92	−7.84	0.43
Social functioning	−4.37	−13.24	0.16
Fatigue	7.1	17.8	0.05
Pain	7.78	24.29	**0.004**
Appetite loss	20.16	37.14	0.07
FACT H&N	−3.02	−4.26	0.33
H&N-B	8.31	14.17	**0.003**

Md, mean differences in scores between two assessments.
Group 1, pain and swallowing < grade 2.
Group 2, pain or swallowing increase to grade 2, 3 or 4 during radiotherapy.

standards of acceptability, reliability and convergent validity. The proportion of missing data was highest with FACT-G, despite it being handed out first. Not surprisingly, the item on satisfaction with the sexual life had the higher rate of missing data. However, this was in part, due to the skip option in the formatting of the question which allows patients not to answer this question. QLQ-C30 had the highest acceptability rating and this may explain the preference of colorectal and breast patients for this questionnaire.

Two FACT-G version 3 items (13 and 21) failed to correlate with the original scales, probably indicating a need for cross-cultural adaptation. However, in version 4, item 13 of version 3 has been changed from a negatively stated ('Family communication about my illness is poor') to a positively stated question ('I am satisfied with family communication about my illness'). Item 21 ('I am proud of how I am coping with my illness') was also reworded and the ambiguous notion of proudness was changed into a more relevant concept of satisfaction ('I am satisfied with how I am coping with my illness'). Notably, the FACT-G 'Relationship With Doctor' subscale has been deleted from version 4, partly due to the ceiling effect as seen here.

QLQ-C30 social subscale scores correlated with FACT-G Physical Well-Being. However, in contrast, the correlation between the QLQ-C30 social subscale and the Social/Family Well-Being domain was very low. This is in accordance with previous findings [17–19] and is probably due to major differences in content: the FACT-G Social/Family Well-Being subscale focuses on social support and emotional closeness, whereas the social functioning items in QLQ-C30 relate to the effects of physical condition on social activities and family life. Poor correlation between the FLIC sociability and the FACT-G social domains is also likely to reflect major differences in content.

The correlation of QLQ-C30 role functioning with FACT-G Physical Well-Being (0.71) was higher than with the Functional Well-Being FACT-G scale (0.50). The QLQ-C30 domain includes items concerning limitations on work, and daily activities, and although FACT-G Functional Well-Being contains similar items, it takes a less concrete, existential approach.

Discriminant value of FACT-G was demonstrated with the significant differences in FACT-G scores observed between patients with different characteristics (gender, marital status, primary tumour and Karnofsky index).

Female patients had lower Physical and Functional Well-Being and global FACT-G scores. This result is consistent with those observed with other questionnaires in this study and with the lower QoL in females in the French general population when measured with the short form-36 (SF-36) questionnaire [20]. The tendency for women to have lower ratings of QoL on EORTC scales was also described in numerous studies [21,22]. Changes in pain and swallowing were also assessed in patients receiving radiotherapy for H&N cancer. The H&N-specific instruments were more responsive to changes that resulted from radiotherapy than the core questionnaires (QLQ-C30 and FACT-G), but worsening of patients' condition was also reflected in a decrease in the FACT-G global score and the EORTC global QoL. This deterioration of QoL in H&N patients during radiotherapy was previously described in [23].

FACT-G Physical and Social Well-Being subscales were sensitive to changes in pain and swallowing for H&N patients. Increase in pain and fatigue, together with radiotherapy constraints and toxicities probably partly explains the deterioration of the Physical and Social Well-Being scores.

There were several limitations to this study. First, the study sample consisted of only three diagnostic groups, breast, colorectal and head and neck cancer patients. There were significant inter-group differences regarding baseline QoL, but the differences established from the questionnaires are apparently related to the different subjects covered, especially for social and role/functional subscales. Another study in 381 patients with chronic lymphatic leukaemia, bone marrow transplantation, breast cancer and Hodgkin's disease also showed only low to moderate inter-correlation between the corresponding subscales of the QLQ-C30 and the FACT-G [18,19].

The major limitation of the study results from the use of the FACT-G version 3 which is now suboptimal. As a matter of fact, significant changes in FACT-G have been made from version 3 to version 4: dropping the 'Relationship with Doctor' subscale, exclusion of the subscale weightings items, changes in the wording of some items. Another French study examined patients' preference for either the QLQ-C30 or the FACT-G version 4 [24]. Sixty-eight patients were recruited and 54% had no preference. However, the FACT-G items were significantly more often perceived as intrusive than the QLQ-C30 items and the unanswered items were also significantly higher for the FACT-G.

In conclusion, the present results show that the characteristics of the French version of FACT-G are similar to those of the original instrument. FLIC, QLQ-C30 and FACT-G subscales were not uniformly correlated, due to differences in item content. QLQ-C30 focuses on the QoL consequences of physical limitations, whereas FACT-G emphasises satisfaction with daily life. The selection of instrument for use in a cancer trial should depend on the fit between its content and the objectives of the investigation.

Conflict of interest

None.

Acknowledgements

We gratefully acknowledge C. Vrousos, M.D., N. Klein, D. Tinchant and C. Dheu for their help in conducting this study which was supported by a Grant from the French government's 'Clinical Research Hospital Programme'.

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