Original investigation

The Psychometric Properties and Clinical Use of the Turkish Version of the Functional Assessment of Cancer Therapy–Lung (FACT-L) Scale

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Cite this article as: Aydoğan BB, Göksel T, Erbaycu AE, Öz A, Çelik P, Kıyar Gürsul K, Çakır Edis E, Hatipoğlu O, Atay Yayla B, Başer S, Baydur H, Eser E. The Psychometric Properties and Clinical Use of the Turkish Version of the Functional Assessment of Cancer Therapy–Lung (FACT-L) Scale. J Basic Clin Health Sci 2019; 3:139-144.

ABSTRACT

Objectives: psychometric properties of the Turkish version of the Functional Assessment of Cancer Therapy-Lung (FACT-L) scale and the sensitivity to changes in clinical indicators.

Patients and Methods: This study was conducted within the framework of a national multicentre project. Patients with either stage IIIB or IV primary lung cancer diagnosed after April 2010were included in thisstudy. A classical confirmatory approach was used for both the reliability and validity analyses. Internal consistency was tested using Cronbach's α value, and the validity analysis was performed using construct validity and clinical validity.

Results: 276 (92.3%) patients were male and the average age was 60.8 ± 9.4 years. The most frequently observed histological type was squamous cell carcinoma (36.8%), and 61.5% of these stage IV tumours. Cronbachs α values for the subscales ranged from 0.60 to 0.84. The majority of the FACT-L subscales revealed inter-scale correlation coefficients greater than 0.35. All sub-dimensions, except that of the social/family well-being scale, are able to significantly discriminate between stages IIIB and IV. Significantly lower scale scores were detected in patients with stage IV than stage IIIB. The comparative fit index was 0.917, and the root mean square error of approximation was 0.091. Dyspnoea, haemoptysis, chest pain, weight loss, anorexia, localised pain, and fever symptoms had a significant correlation with the FACT-L, trial outcome index, and lung cancer subscale.

Conclusion: Turkish version of the psychometric properties of the original FACT-L scale is regarded as a valid and reliable tool and can be used safely in a clinical context when managing patients with lung cancer in Turkey.

Keywords: Lung cancer, quality of life, FACT-L

INTRODUCTION

Lung cancer is the leading cause of cancer-related death and the most common type of cancer among Turkish men (1). Despite all treatment modalities, the median survival is 5 to 10 months, even in patients with non-small cell lung cancer (2–3). Whilst the survival period is currently used as an objective outcome for evaluating lung cancer control/management programs, health-related quality of life (HRQOL) has also become important as a supplementary patent-reported outcome in recent years. A number of previous reviews and papers have noted that the added value of HRQOL does not correlate well with the biomedical outcomes in lung cancer trials.

Globally, a significant proportion of the research concerning HRQOL has been carried out through international clinical

research, particularly in Western societies. Therefore, although the majority of patients with cancer, especially lung cancer, are treated in developing countries, the factors that determine quality of life in cancer research have been mostly restricted to Western cultures. The first stage in the cross-cultural comparison of treatment outcomes in cancer is the availability of valid measurement tools, both generic and cancer-specific. The European Organization for Research and Treatment of Cancer (EORTC QLQ-C30) scale, as a generic quality of life questionnaire for patients with cancer, has been used for a couple of years in Turkey (4), and the most commonly used lung cancer-specific quality-of-life scales are the European Organization for Research and Treatment of Cancer Quality of Lung Cancer (EORTC QLQ-LC13) and the Functional Assessment of Cancer Therapy-Lung (FACT-L). The FACT-L was developed by the Functional Assessment of Chronic Illness Therapy (FACIT) group and is known to have been adapted to many languages and cultures (5–12). The FACT-L has been one of the most useful tools in the prediction of subsequent survival of patients with lung cancer. Butt et al. (13) demonstrated the development of, and a wide range of use of, the FACT-L in their review.

The aim of this study was to investigate the psychometric properties of the Turkish version of the FACT-L scale and its sensitivity to any changes in the clinical indicators.

METHODS

Study Design and Subjects

This methodological prospective study was carried out within the framework of a national multicenter project entitled the 'Turkish Lung Cancer Quality of Life Project (AKAYAK-1)' , which was conducted by the Turkish Thoracic Society and the Turkish Association of Health Related Quality of Life (SAYKAD). A representative sample of 299 patients with lung cancer recruited from five regional comprehensive centers in Turkey comprised the study population. The breakdown of the total number of patients in this study is as follows: 103 patients from the Ege University Faculty of Medicine Department of Chest Diseases, 92 from the Celal Bayar University Faculty of Medicine Department of Chest Diseases, 63 from the Izmir Dr. Suat Seren Chest Diseases and Thoracic Surgery Training Hospital, 23 from the Trakya University Faculty of Medicine Department of Chest Diseases, and 18 from the Pamukkale University Faculty of Medicine Department of Chest Diseases. This AKAYAK project was approved by the Research Ethics Committee of Ege University (reference no: 10–6/6, date: 01.07.2010).

Inclusion Criteria
- Patients with primary lung cancer diagnosed as stage IIIB or IV (including all histological types)
- Patients previously untreated and planned to undergo chemotherapy, radiotherapy (RT), or chemo-radiotherapy
- Patients able to read and complete the forms, who agreed to attend the study, and who agreed to come to control visits
- Patients who signed the written informed consent form

Scale
The FACT-L was developed and published by David Cella et al. in 1995. It is a combination of a generic cancer scale, the Functional Assessment of Cancer Therapy-Generic (FACT-G), and a 'lung cancer subscale' (LCS) and comprises 37 questions (6, 14) with a 4-point Likert-type response scale. Generic subscales and the item compositions of the FACT-G are as follows: physical well-being (PWB) (7 items), social/family well-being (SWB) (7 items), emotional well-being (EWB) (6 items), and functional well-being (FWB) (7 items). The 10-item LCS is used to assess lung cancer symptoms. The trial outcome index (TOI) is a 21-item single score that was proposed for the assessment of the physical components of HRQOL in clinical trials. It sums the PWB, EWB, and LCS subscales of the FACT-L (13). The total possible range of scores ranges from 0 to 84. Higher scores refer to a better quality of life (11). Reliability and validity analyses were performed after permission was obtained from the FACIT agency to use the official Turkish version of the FACT-L scale (version 4) dated 21.10.2010.

Data Collection
The FACT-L scale was completed by the patient during each visit before examination by a doctor. Following completion of the diagnostic procedures, the questionnaire battery consisting of socio-demographic information and the quality-of-life questionnaires was applied by the physicians during the initial visit.

Patients who were treated with chemotherapy alone were asked to complete the FACT-L before the third and fifth treatment cycle, whereas those patients receiving only RT or chemo-RT were asked to complete it before the onset of therapy and 3 weeks after therapy. During these visits, the Karnofsky Performance Scale (KPS) and Eastern Cooperative Oncology Group (ECOG) scores were also applied to all patients by the physicians.

Statistical Analysis
A confirmatory approach was used for both reliability and validity analyses. Internal reliability analyses were conducted following item frequency distributions and item-subscale correlations.

Internal consistency was tested using Cronbach's α, whereas item-scale and item-total score relationships were explored using Pearson and Spearman correlation analysis, where appropriate.

Validity analysis was conducted using construct validity and clinical validity (responsiveness to change) methods. The construct validity of the scale was tested by 1) convergent-divergent validity, 2) known groups validity, and 3) confirmatory factor analysis. To show the convergent-divergent validity of the FACT-L, we explored the inter-correlation of the subscales of FACT-L and hypothesized that conceptually related subscales would be highly correlated with each other rather than unrelated ones. The known groups validity was tested with regard to the existing symptoms and the subcategories of the ECOG and KPS scores. Student's t-test and one-way analysis of variance were employed during

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these analyses. We tested the fit of the structure of the Turkish version with that of the original construct using confirmatory factor analysis. The confirmatory fit index (CFI) and the root mean square error of approximation (RMSEA) were used to show the level of fitness.

Clinical validity was assessed by longitudinal score changes in time along with the disease stage and patient performance (ECOG and KPS) scores. Analyses were conducted using SPSS for Windows version 15.0 (SPSS Inc., Chicago, USA) and Lisrel version 8:05 (15).

RESULTS

Of the total study population, 276 (92.3%) patients were male and 23 (7.7%) were female, with an average age of 60.8±9.4 years. In total, 87.6% of the patients were married and 97.9% were covered by social health insurance. The demographic properties of the study sample, clinical characteristics, histological type of tumour, and tumour stage are shown in Table 1. The most frequently observed histological tumour type was squamous cell carcinoma (36.8%), and 61.5% of these were stage IV tumours. At diagnosis, the most common symptoms were cough (65.9%), dyspnoea (55.2%), and weight loss (53.8%). The median KPS and ECOG scores were 90% and 1.0, respectively. The number of stage IV

patients enrolled in a chemotherapy programme was 140. The remaining 44 patients had undergone palliative RT and were awaiting chemotherapy. Thirty-six of 115 patients with stage IIIB cancer had previously undergone aggressive RT, whilst the remaining 79 were offered chemo-RT.

In total, 34.4% of the study patients were identified to have at least one comorbid disease, most frequently diabetes mellitus, hypertension, and chronic obstructive pulmonary disease. Longitudinal quality-of-life assessment was unable to be made in 26.4% of the patients (those who could not complete the treatment and/or were lost to follow-up).

Reliability Results

The item scale correlations showed good item success. All items provided higher and significant correlation coefficients with their own subscale scores compared with that of other subscales, except items 5 (hair loss) and 9 (smoking) of the LCS and item 7 (sex life) of the SWB scale (data not shown).

Cronbach's α for the subscales ranged from 0.60 to 0.84. All α values were greater than 0.70, except for the LCS (0.60) (Table 2). 'If item deleted' α values revealed that all items, except item 7 of the SWB scale, item 2 (coping with illness) of the EWB scale, item 3 (enjoy life) of the FWB scale, and items 5 and 9 of the LCS, significantly contributed to the variances of their subscales.

Construct Validity Results (convergent-divergent validity)

The convergent and discriminant evidence was explored by inter-scale correlations of the instrument. The majority of FACT-L subscales revealed inter-scale correlation coefficients of greater than 0.35. Lower correlation figures were obtained between PWB and SWB (r=-0.017), SWB and LCS (r=0.046), and SWB and TOI (r=0.101). We found mutually strong inter-correlations between the overall FACT-L score, TOI score, and FACT-G total scores and its subscales (Table 2).

Construct Validity Results (known groups validity)

The known groups validity was tested by considering the associations between the FACT-L and symptom presentation, ECOG score, and KPS score. Dyspnoea, haemoptysis, chest pain, weight loss, anorexia, localized pain, and fever were observed to have a

Table 1. Demographic and tumor characteristics of the cases

Age (median ± SD)	60.8±9.4
Gender, n (%)	
Male	276 (92.3)
Female	23 (7.70)
Comorbid conditions, n (%)	103 (34.4)
Histological type of tumor, n (%)	
Squamous cell	110 (36.8)
Adenocarcinoma	69 (23.1)
Small cell	61 (20.4)
Nonsmall cell	36 (12.0)
Radiological tumor	11 (3.0)
Unclassified tumor	7 (2.3)
Large cell	5 (1.6)
Stage of tumor, n (%)	
Stage IIIB	115 (38.5)
Stage IV	184 (61.5)

Table 2. Inter-scale correlations of FACT-L

	Cronbach's alpha	PWB	SWB	EWB	FWB	FACTG	LCS	FACT-L
PWB	0.84	1						
SWB	0.72	0.017	1					
EWB	0.83	0. 496**	0. 337**	1				
FWB	0.80	0. 650**	0. 188**	0. 560**	1			
FACT-G	0.60	0. 779**	0. 472**	0. 807**	0. 850**	1		
LCS	0.81	0. 593**	0.046	0. 346**	0. 515**	0. 537**	1	
FACT-L	0.80	0. 807**	0. 406**	0. 764**	0. 844**	0. 975**	0. 711**	1
TOI	0.79	0. 886**	0.101	0. 556**	0. 860**	0. 858**	0. 805**	0. 927**

* Pearson correlation coefficient *p<0.05, **p<0.01

Table 3. The variability of FACT-L scale according to presence or absence of lung cancer symptoms

Symptom	PWB effect size	SWB effect size	EWB effect size	FWB effect size	LCS effect size	FACT-G effect size	FACT-L effect size	TOI effect size
Cough	ns*	0.20†	ns	ns	0.67††	ns	ns	0.31†
Dyspnea	ns	ns	ns	ns	1.00††	ns	0.39††	0.53††
Chest pain	0.27†	ns	ns	0.39††	0.58 ††	0.35†	0.45††	0.48††
Hemoptysis	ns	ns	ns	ns	0.48††	ns	0.37†	0.30†
Anorexia	0.64††	ns	ns	0.51††	0.89††	0.41††	0.68††	0.82††
Weight loss	0.64††	ns	ns	0.4††	0.71††	0.43††	0.60††	0.75††
Fever	0.54††	0.47††	0.52††	0.47††	0.61††	0.67††	0.72††	0.61††
Localized pain	0.70††	ns	0.25†	0.36†	0.25†	0.48††	0.47 ††	0.53††
Hoarseness	0.40 ††	ns	0.38††	ns	0.51††	0.29†	0.38††	0.39††

*Student's t test; ns=non-significant; †=p<0.05; ††=p<0.01

Table 4. The correlations between FACT-L scale with ECOG and KPS

	ECOG	Karnofsky
PWB	-0.501 (**)	0.482 (**)
SWB	0.081	-0.178 (**)
EBW	-0.261 (**)	0.154 (**)
FWB	-0.478 (**)	0.470 (**)
FACT-G	-0.426 (**)	0.354 (**)
LCS	-0.369 (**)	0.401 (**)
FACT-L	-0.451 (**)	0.400 (**)
TOI	-0.532 (**)	0.532 (**)

*Spearman correlation: *p<0.05, **p<0.01

significant correlation with the FACT-L, TOI, and LCS (Table 3). The relationship between the subscales of the FACT-L and ECOG with the KPS can be seen in Table 4. Strong correlations were obtained among the scales of the FACT-L and the ECOG and KPS, except between the ECOG and SWB scales.

Factor analysis
The confirmatory factor analysis results showed that the fitness of the Turkish version to the original scale structure was within acceptable limits: the CFI was 0.917 and the RMSEA value was 0.091.

Clinical Validity Results
This approach may be called 'responsiveness to change' or 'susceptibility to different levels of disease severity' . Therefore, if the clinical condition of the patient improves, better scores would be expected to be obtained, and vice versa. All subdimensions except that of the SWB scale could significantly discriminate between stages IIIB and IV. Significantly lower scores were detected in patients with stage IV than IIIB (Table 5). The distribution of the scores of the FACT-L according to the categories of the ECOG (≥2 vs 0–1) were also tested (not shown in the tables). Statistically significant differences were obtained between these two ECOG categories in all subscale scores of the FACT-L.

DISCUSSION

The growing need to use reliable and valid quality-of-life instruments for lung cancer management in Turkey, a country with a high prevalence of smoking (16) and a very high incidence of lung cancer (17), prompted us to translate and validate the FACT-L along with other HRQOL instruments that will be discussed elsewhere. This multicenter study comprised all newly diagnosed patients during a 1-year period. The cooperation of patients in this study was good, and most items had a very limited

Table 5. The change of FACT-L scores according to tumor stage

	Tumor stage	n	Mean ± SD	t	p
PWB	IIIB	110	20.9±5.7		
	IV	184	17.6±6.2	4.522	**0.000
SWB	IIIB	110	24.0±4.6		
	IV	184	23.1±5.0	1.582	0.115
EWB	IIIB	110	19.1±4.7		
	IV	183	16.8±5.4	3.590	**0.000
FWB	IIIB	110	18.8±5.6		
	IV	184	16.0±6.5	3.743	**0.000
FACT-G	IIIB	110	82.8±16.0		
	IV	183	73.5±16.5	4.712	**0.000
LCS	IIIB	110	19.5±5.2		
	IV	184	18.2±5.3	2.189	*0.029
FACT-L	IIIB	110	102.3±19.7		
	IV	183	91.7±19.6	4.492	**0.000
TOI	IIIB	110	59.2±15.0		
	IV	184	51.7±14.8	4.177	**0.000

*p<0.05, **p<0.01

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amount of missing data, implying good patient acceptance and understanding of our translation.

The FACT-L, TOI, FACT-G, PWB, and SWB scores were found to be lower in this study than in the results of the original study by Cella et al. (6). The only exception was the higher scores obtained for EWB in our sample. The LCS score from the Turkish version was also found to be higher than the original study results. However, the baseline results from a Brazilian validation study were better than our sample, except for the SWB scores (12). This could be attributed to the cultural differences and different social support mechanisms between the two countries. A higher dimension score was also reported for SWB in the South Korean version (8).

The internal consistency of the Turkish version of the FACT-L scale is compatible with the results of the main questionnaire designed by Cella et al. The lowest internal consistency (α) value was obtained for the LCS scale (0.60) in our study, which was also found to be lower than 0.7 in the FACT-L studies by Cella et al. (6, 18, 19) and Browning et al. (20) and in the South Korean and Japanese versions (8, 21). A lack of change in the α coefficients following the removal of each item showed that all items of the LCS, except for item 3 (thinking), item 5 (bothered by hair loss), and item 9 (smoking), were consistent with the entire questionnaire. Item total correlations also revealed that the above-mentioned items were more highly correlated with the SWB (social life) dimension than their own dimensions. It is to be expected that hair loss and regret of smoking are closely associated with social life.

The construct validity of the FACT-L was tested using convergent validity, factor analysis (SEM) and known groups validity approaches. Acceptable convergent (TOI vs PWB, EWB, and FWB) and divergent (PWB vs SWB; LCS vs SWB) validity results revealed good construct validity for the FACT-L. Confirmatory factor analysis results (CFA and RMSEA) were also indicative of an acceptable fit for the Turkish version compared with the original factor structure.

The known groups validity of the Turkish FACT-L was tested by independent external variables such as the existence of symptoms and performance indicators (ECOG and KPS). It was found that the TOI is more sensitive to symptom experience than are the individual dimensions. The TOI, as a combination of the PWB, EWB, and variety of effect sizes, was obtained by the TOI for each of the lung cancer symptoms. Regarding performance scales such as the ECOG and KPS, all dimensions except for the SWB and partial EWB dimensions were found to be sensitive to performance indicators. Additionally, it was observed that the TOI was most closely correlated with performance scores and therefore best able to reflect the parameters of lung cancer symptoms.

In the present study, the TOI was better correlated with the performance scores and therefore best reflected the parameters related to lung cancer symptoms. Due to problems such as disease-related symptoms, side effects, and physical ability, the TOI reflects the effect of cancer-related quality of life best and minimizes the errors of three subdimension measurements. It is therefore able to emphasize the most sensitive parameters.

When considering the variability of the FACT-L scale according to the presence or absence of lung cancer symptoms, the symptoms of dyspnoea, haemoptysis, chest pain, weight loss, anorexia, localized pain, and fever have meaningful relationships with the FACT-L, TOI, and LCS scores as was shown in detail by their effect sizes. It was found that the presence of all symptoms was associated with the lung cancer-specific subgroup of symptoms involving LCS. All symptoms of lung cancer at this size of LCS indicate the efficacy of the assessment ($p>0.01$, effect size: 0.25–1.00). The total FACT-L and TOI scores including the LCS are also associated with all symptoms of lung cancer ($p>0.01$; effect size, 0.30–0.82). Our findings were in line with the literature; for example, Smith et al. found that patients with severe dyspnoea had a lower mean FACT-L score ($p=0.04$) (22).

Most frequently, the ECOG and KPS have been used by physicians treating patients with lung cancer to evaluate the performance scale. In our study, a negative correlation between KPS and SWB was observed. A strong correlation was observed among all other subdimensions. Excluding the ECOG and SWB, a meaningful correlation was again seen among all subdimensions.

When considering the stage of the tumour, the scale scores varied significantly in all dimensions among patients with stage IIIB cancer, although SWB scores were lower in patients with stage IV disease. In a study conducted by Yoo et al. (8), the scale scores at diagnosis were compared between patients with stage I-IIIA and IIB cancer. While differences were detected according to the stages in the FACT-L, FACT-G, TOI, SWB, and EWB, no differences were detected in the PWB or FWB. In the present study, in the evaluation at diagnosis excluding SWB, differences were detected in all dimensions even in patients with advanced disease (stage IIIB-IV).

When considering the change in scale scores according to the ECOG (≥2 and 0–1), the scale scores of all subscales showed statistically significant differences according to the scale scores of patients whose ECOG score was ≥2 or ≤1. The performance evaluation implemented by the physician is compatible with the results of the scale scores.

This study had various limitations. The main limitation was the lack of a control group. A control group could be obtained by snowball sampling of peers or friends of the patients, but this could also increase the difficulty of recruiting patients to the study because it was very difficult to involve patients in the study in the first place. The other limitation was the inadequacy of the sample size. Due to time constraints, the required sample size was not achieved. Another limitation was our inability to assess the instruments in two consecutive instances (test-retest). This was due to the progressive nature of lung cancer, so test-retest could not be verified. Additionally, surveys were carried out during the days when chemotherapy was administered after the first week of treatment because it was thought that the emotions and concerns of patients who underwent chemotherapy could affect EWB. Chemotherapy days were preferred to evaluate quality of life because lung cancer (and its treatment) is a condition that can make people more distressed both physically and mentally/spiritually. However,

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completing the questionnaire during chemotherapy administration had no effect on the EWB score in the present study.

This multicenter study increased the possibility of involvement of a range of patients with lung cancer from a variety of cultures and allowed us to conclude that the Turkish version of the psychometric properties of the original FACT-L scale can be regarded as a valid and reliable instrument and can therefore be used safely in a clinical context during the management of patients with lung cancer in Turkey.

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