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A Psychometric Analysis of Quality of Life Tools in Lung Cancer Patients Who Smoke

Kristine K. Browning, PhD^{*,1,2}, Amy K. Ferketich, PhD¹, Gregory A. Otterson, MD^{2,3}, Nancy R. Reynolds, PhD⁴, and Mary Ellen Wewers, PhD, MPH¹

¹The Ohio State University College of Public Health

²The Ohio State University Comprehensive Cancer Center

³The Ohio State University College of Medicine

⁴Yale University School of Nursing

Abstract

Lung cancer is the leading cause of cancer death for both men and women in the United States. Patient quality of life (QOL) prior to cancer treatment is known to be a strong predictor of survival and toleration of treatment toxicities. A lung cancer patient's self-assessment of QOL is highly valued among clinicians as it guides treatment-related decisions and impacts clinical outcomes. Smokers are known to report a lower QOL. Limited research has been conducted on QOL outcomes in lung cancer patients who continue to smoke.

To assess QOL, a reliable and valid QOL measure specific to lung cancer is required. The Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L) and Lung Cancer Symptom Scale (LCSS) are instruments that specifically examine QOL among lung cancer patients. The LCSS is a focused QOL instrument that includes physical and functional domains of QOL and disease symptomatology. The FACT-L is a broader QOL instrument that includes physical, functional, social and emotional domains and disease symptomatology. Both are psychometrically valid and are widely used in the literature, but have not been exclusively evaluated in smokers. Furthermore, there is no 'gold standard' instrument since there has never been a correlation study to compare estimates of reliability and validity between these instruments. The purpose of this study is to report the internal consistency and convergence validity of the FACT-L and the LCSS among newly diagnosed lung cancer patients who smoke.

This data were collected and analyzed from a larger study examining smoking behavior among newly diagnosed lung cancer patients (n=51). Descriptive statistics were calculated on the FACT-L and LCSS scores, internal consistency was assessed by estimating Cronbach's alpha coefficients, and Pearson correlation coefficients were estimated between the two scales. Internal consistency coefficients demonstrated good reliability for both scales, and the two instruments demonstrated a strong correlation, suggesting good convergence validity. Either of these instruments are appropriate

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*Corresponding Author & Reprints: Kristine Browning, The Ohio State University College of Public Health, 434 Cunz Hall, 1841 Neil Avenue, Columbus, Ohio 43210, Ph: 00+1.614.292.3156, Fax: 00+1.614.293-3370, browning.99@osu.edu.

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Conflict of Interest Statement

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measures for QOL in lung cancer patients who smoke. Given the conceptual difference between the two instruments, it is important to carefully consider the research aims when selecting the appropriate QOL measurement instrument.

Keywords

Quality of life; smoking; tobacco use; lung cancer; questionnaire; psychometric analysis

Background

Lung cancer is the leading cause of cancer death for both men and women in the United States, responsible for approximately 160,390 deaths in 2007 (1). The 5 year survival rate for all stages of lung cancer is poor, approximately 15.5% (2). Surgery, chemotherapy, and/or radiation therapy are the cornerstones of treatment for lung cancer, all of which directly contribute to patient quality of life (QOL) (3). A lung cancer patient's self-assessment of QOL is highly valued among clinicians as it guides treatment-related decisions and impacts clinical outcomes (4). More than half of lung cancer patients are diagnosed in the advanced stages of the disease and chemotherapy is the primary indicated treatment (3,5). Patient performance status and QOL prior to cancer treatment are known to be strong predictors of survival and toleration of treatment toxicities. For patients with advanced lung cancer with a poor prognosis, the goal of treatment is improvement in QOL and disease-related symptomatology (6). While treatment can improve disease related QOL and symptoms, it can also deliver treatment related symptoms which may impair QOL. To assess improvement, a reliable and valid QOL measure specific to lung cancer is required.

QOL is a multidimensional construct that includes physical, functional, social, psychological, and spiritual domains (7,8). Research aims should guide instrument selection based on QOL components that are necessary for evaluating study outcomes (9). For example, to accomplish the research aims of a chemotherapy clinical trial a QOL tool that measures physical and functional domains may be required to assess treatment-related toxicities. Achievement of other research aims may require a broader representation of QOL, including social and psychological domains. Other factors such as length and subject burden may also be important to consider when selecting a QOL instrument.

There are several accepted disease and site specific instruments that are used to measure QOL in lung cancer patients (9). The *Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L)* is a multi-dimensional QOL self-report instrument that is specific to lung cancer and includes five subscales. A core component (FACT), consisting of four subscales, is designed to measure general cancer-related QOL, including components of the physical, functional, social, and emotional domains of QOL (10,11). The addition of a lung cancer scale, which is designed to measure symptomatology related to lung cancer, comprises the FACT-L. FACT-L version 3 is the most recent psychometrically tested version of the instrument (10). The *Lung Cancer Symptom Scale (LCSS)* is another lung cancer specific self-report QOL instrument. This instrument is more focused as it only includes components of the physical and functional domains of QOL and lung cancer symptomatology (12). These tools have been utilized for measurement of patient reported QOL in many chemotherapy clinical trials (9).

The relationship between QOL and smoking has been reported in the literature. Tobacco use is the strongest risk factor for developing lung cancer (13). Eighty-seven percent of lung cancer patients have a history of smoking (current or ex-smokers) and approximately 13–20% of current lung cancer patients continue to smoke after diagnosis (14–17). Findings from a population-based study of 3,010 participants, indicated that smokers had a significantly lower

QOL than former smokers; heavier smokers had a significantly lower QOL than lighter smokers (the SF-36 was used to measure QOL in this study) (18). Tillmann et al. (19), in a study of 1,665 individuals from nine primary care practices, found that current smokers had a lower self-rated QOL than former smokers (the SF-36 was used to measure QOL in this study).

To date, only one study has been conducted to examine QOL in lung cancer patients who *currently smoke*. In this cross sectional study, QOL was examined at ≥ 6 months after diagnosis in 1,028 patients (20). Persistent smokers had a significantly worse QOL than never smokers as measured by the LCSS (20). Former smokers (i.e., those who quit before diagnosis) and abstinent smokers (i.e., quit between diagnosis and follow-up period) had LCSS scores similar to never smokers, which further supports an association between continued smoking and a lower QOL.

It has been demonstrated that current smokers experience a lower quality of life (18,19). Since QOL is an important outcome measure for clinicians when assessing response to lung cancer treatment (4,6), and a proportion of lung cancer patients continue to smoke after diagnosis, it is important to closely examine QOL among lung cancer patients who continue to smoke. The psychometric properties of the FACT-L and the LCSS QOL scales have been well studied, but have not been examined exclusively in smokers (10–12,21). Demonstrating these properties in a cohort of smokers would strengthen the utility of these instruments in future studies. In future studies a comparison of mean scores from these instruments (with lung cancer patients who smoke) could be analyzed.

The FACT-L contains items that are conceptually different from the LCSS in measuring QOL in lung cancer patients. To date, a ‘gold standard’ instrument that measures QOL among lung cancer patients has not been identified since there has never been a comparison study examining the correlation between these QOL instruments. The LCSS is the only QOL tool that has measured QOL in lung cancer patients who smoke but its internal consistency has not been reported. The purpose of this study is to report the internal consistency and convergence validity (i.e., measure of constructs that should be theoretically related to each other) of the FACT-L and the LCSS among newly diagnosed lung cancer patients who smoke.

Methods

Design/Sample

The data for this analysis came from a prospective, one-group longitudinal study designed to describe sociodemographic and behavioral characteristics, illness representation, and quality of life among recently diagnosed lung cancer patients who smoke ($n=53$). Patients were eligible if they were age 18 years or older, had a confirmed diagnosis of lung cancer (non-small cell or small cell) within the past 60 days, and self-reported current smoking within the past seven days. Patients had to be able to understand English and provide informed consent. Recruitment took place within the thoracic oncology outpatient clinics at The Ohio State University Comprehensive Cancer Center (OSUCCC), an urban, academic, tertiary care medical center. At baseline and 6 months following enrollment, patients completed a series of questionnaires, including the QOL tools FACT-L and LCSS. Verbal and written instructions for the questionnaires were given to each patient. This study was approved by and in compliance with the institution’s Human Subjects Cancer Review Board. Only the baseline QOL data is presented here.

Study Measures

Patient sociodemographic, lung cancer, and tobacco use history variables were collected upon study entry. Sociodemographic variables included: age, gender, insurance type, education,

race/ethnicity, marital status, and household income. Histology, stage, and any prior treatment for the current diagnosis were the lung cancer variables. Tobacco use variables included cigarettes smoked per day (CPD), number of years smoked, number of serious quit attempts, and the Fagerström Test for Nicotine Dependence (FTND), an accepted, reliable self-report measure of nicotine dependence among current smokers (22).

Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L)—The FACT-L (version 3) is a reliable and valid 44-item paper and pencil self-assessment questionnaire that measures QOL over the past week in patients with lung cancer (10). It has been widely used in clinical trials that are conducted to evaluate symptoms and QOL in clinical trials with lung cancer patients (23). The FACT-L is made up of five subscales that include physical well-being (PWB), social/family well-being (SWB), emotional well-being (EWB), functional well-being (FWB), and symptoms of lung cancer scale (LCS). Each question is rated on a five-point Likert scale giving a total score for each category as well as a total overall score (0–135). A higher score corresponds to a higher (better) QOL. The Trial Outcome Index of the FACT-L (FACT-L TOI), which is the sum of the PWB, FWB and LCS scales, is a measure of the physical aspects of QOL and often utilized in chemotherapeutic clinical trials to evaluate patient QOL and symptomatology related to study medication.

If any items of the FACT-L are omitted, a score can still be estimated for the subscale as long as the majority of items within a subscale have been answered. Internal consistency (Cronbach's alpha) has been reported to be 0.68 for the LCS subscale, 0.87 for the total core scale (PWB + FWB + SWB + EWB), and 0.89 for the FACT-L TOI (PWB + FWB + LCS) (10). Test-retest reliability for the total core scale was reported as 0.92 (11). Construct validity was demonstrated as high, reflecting good convergence and discriminant validity with appropriate scales (10,11). The sample for this psychometric testing included lung cancer patients (n=116) who either participated in the initial FACT instrument validation or were part of a psychosocial quality of life study (10). Thus, this sample of patients was not limited to smokers, which is different from our study.

The Lung Cancer Symptom Scale (LCSS)—The LCSS is a reliable and valid disease and site-specific QOL measure which consists of nine visual analogue scales (0–100mm) assessing QOL in the past 24 hours (12). The 9-scale mean total represents the overall score, with a lower score corresponding to a better QOL. These scales focus on physical and functional dimensions only, including six major symptoms of lung cancer: appetite, fatigue, cough, dyspnea, hemoptysis, and pain. The remaining three items include a self rating of general lung cancer symptoms, how illness affects normal activities of daily living, and overall QOL (12).

The LCSS has good reliability with reported internal consistency of 0.82, a high reproducibility as indicated in test-retest reliability (n=52 lung cancer patients, $r>0.75$), and high repeated inter-rater agreement among experts (95%–100% agreement) (21). Validity has also been established for the LCSS. Lung cancer experts, that included 24 medical oncologists and 28 nurses, confirmed representation of items for content validity and 121 patients with advanced lung cancer were surveyed to validate the major symptoms of lung cancer. Results of the expert panel indicated a mean of 96% agreement for all items and lung cancer patients confirmed that symptoms matched their experiences (12). Good convergence with a similar QOL tool and discrimination with unrelated tools demonstrated good construct validity (12). Criterion-related validity (i.e. correlation with a gold standard measure) was satisfactorily demonstrated with several significant correlations between tools (e.g., Sickness Impact Profile, Profile of Mood States, American Thoracic Society, SF-McGill Pain, and Karnofsky Performance Scale) (12). Similar to the FACT-L, the LCSS properties have not been examined among current smokers.

Statistical Analysis

Descriptive statistics (percents, means, and standard deviations) were calculated on all sociodemographic, lung cancer, and tobacco use variables and on the FACT-L and LCSS scores. Internal consistency was assessed by estimating Cronbach's alpha coefficient on the FACT-L and LCSS items (24). Pearson correlation coefficients were estimated between the total FACT-L and the LCSS, the FACT-L TOI and the LCSS, and each FACT-L subscale and the LCSS. Scatter plots were created to visually represent the relation between each pair of scales named above and to illuminate both good and poor relations between the scales. A regression model was fit to each pair of scales in order to further describe the relation between the pairs. The regression model residuals were examined to determine if the assumption of normality was met. To assess for model deficiency, residual plots were examined to identify outliers (25). All data were analyzed using SPSS 14.0 (SPSS Inc, Chicago, IL).

Results

Sample Characteristics

Fifty-one subjects completed the FACT-L and 50 subjects completed the LCSS at study entry (see Table 1 for sample characteristics). The average age of the sample was 57 years (SD=10.2). About half of the sample was male (49%) and married (51%), and the majority was white (84%). Thirty-seven percent of subjects reported education of some college or more and 25.5% reported only having a high school education. The majority was diagnosed with late stage non-small cell lung cancer and was treatment naïve. The average number of cigarettes smoked per day by participants was 16 and the average number of years smoked was 37 years. The sample reported an average of 5.0 previous quit attempts, with an average FTND score of 5.0, indicating moderate nicotine dependence.

Scale Characteristics—The descriptive statistics of patient scores from the QOL scales are presented in Table 2. The mean total FACT-L score was 81.1 (range 34–123) and the FACT-L TOI (PWB + FWB + LCS) mean score was 46.3 (range 14–76). The mean score for the LCSS was 40.0 (range 9.9–86.3). In the FACT-L, a *higher* score corresponds to a higher (better) QOL, and in the LCSS, a *lower* score corresponds to a higher (better) QOL. Mean scores for the total FACT-L, FACT TOI, and LCSS by subgroups (treatment naïve vs. treatment and early vs. late stage lung cancer) are presented in Table 3.

Internal consistency coefficients for the FACT-L, FACT-L subscales and LCSS are presented in Table 4. The PWB, SWB, FWB, and EWB scales all demonstrated good reliability with Cronbach's alpha coefficients of 0.81 or higher. The internal consistency coefficient for the LCS scale was lower, 0.61. The FACT-L TOI scale, the total FACT-L scale, and the LCSS each indicated good reliability with coefficient alphas of 0.88, 0.87, and 0.84 respectively. One-third of participants omitted a response to an item on the SWB subscale of the FACT-L that asks about intimacy. Due to missing data, the number of participants included in the item analyses for the total FACT-L and its SWB subscale was lower.

Comparison of QOL Scales

The FACT-L subscale with the strongest correlation to the LCSS was the LCS ($r = -0.78$). The total FACT-L and the FACT-L TOI also were strongly correlated with the LCSS ($r = -0.73$ and $r = -0.76$, respectively). Scatter plots illustrating these relationships are presented in Figure 1. The remainder of the FACT-L subscales (PWB, SWB, EWB, and FWB) had weaker correlation with the LCSS ($r = -0.67$, $r = -0.21$, $r = -0.27$, and $r = -0.54$, respectively). The correlations were negative because a higher score on the FACT-L represented a better QOL and conversely, a lower score on the LCSS represented a better QOL. The regression model residuals were examined for each pair of scales. Each plotted residual reflected normal data

characteristics in the histograms and normal probability plots, and no model defects were detected in the residual plots.

Discussion

This paper was the first to report internal consistency and convergence validity for the FACT-L and the LCSS QOL instruments in a sample of lung cancer patients who smoke. It has been demonstrated that smokers have a lower QOL, and assessing QOL in lung cancer patients is an important clinical outcome. Internal consistency scores were high for each FACT-L component (except for the LCS) and the LCSS, demonstrating good reliability among a sample of lung cancer patients who smoke. Establishing good reliability in a cohort of smokers will allow for comparison that is based on accurate assessment in future studies. The internal consistency scores for the LCSS and FACT-L and its components in this study were similar to data previously reported in the literature (10–12,21,23). The lower internal reliability of the LCS (subscale of the FACT-L) is similar to existing reports (10,11,23). The FACT-L and the FACT TOI were both strongly correlated with the LCSS, supporting good convergence validity. The FACT-L TOI, which is the most conceptually-related FACT-L measure to the LCSS, demonstrated the strongest correlation. The emotional and social well-being subscales of the FACT-L demonstrated low correlation with the LCSS. Conceptually this was expected as emotional and social well-being domains are not represented components of the LCSS. This further supports the strong correlation between both instruments.

The mean scores reported in this paper for the FACT-L and its components and the LCSS corresponded with a lower (worse) QOL than reported mean scores in the literature (10,26, 27). Garces et al. (20) reported adjusted mean scores for the total LCSS and individual item scores that were approximately ten points lower, representing a higher (better) QOL than the LCSS mean scores reported in this study (see Table 5). Current study participants included newly diagnosed (within 60 days) lung cancer patients who were smokers and the Garces et al. study included smokers who had been diagnosed for 6 months or more, suggesting a sample of both lung cancer survivors and patients who completed treatment. Sixty percent of the sample in the current study was treatment naïve and could have been experiencing disease-related symptoms at baseline, contributing to a worse QOL. Also, 40% were currently undergoing treatment and could have been experiencing treatment-related side effects, further affecting QOL. Garces et al. (20) did not indicate the percent that was currently undergoing lung cancer treatment. The majority of patients in the current study (66%) had late stage lung cancer compared to 30% of patients in the Garces et al. (20) study. The inclusion of fewer late stage lung cancer patients could potentially contribute to the reported overall better QOL.

The LCSS measures QOL over the past 24 hours whereas the FACT-L measures QOL over the past week. This difference in time interval may limit comparisons of these two measures; however the correlations between the two scales remain high. Accurately portraying a patient's QOL should include subjective, open-ended questioning. Neither the FACT-L nor the LCSS allow for such patient input. However, using the research aims to guide the research methods and the selection of a QOL assessment instrument is important. It is crucial to characterize change in QOL over a period of time, requiring use of a QOL measurement such as the FACT-L or the LCSS. The LCSS is a visual analogue scale and some patients have difficulty understanding how to mark a visual analogue scale, even with instruction (28). Participants tend to mark similar places along the visual analogue line, regardless of intended response (28). The short length of the LCSS (9-items) and the narrow focus on only physical and functional components of QOL is useful when evaluating specific side effects of treatment (such as chemotherapy). However, the brevity and narrow focus may limit an evaluation of overall QOL (29).

Conclusion

Findings from this study can be used to describe QOL in lung cancer patients who smoke. This type of information can be useful to clinicians who are trying to motivate smokers to quit. It also should encourage clinicians to make smoking status an important consideration when evaluating treatment toxicities as they relate to QOL.

QOL is an important construct that is routinely assessed in clinical oncology practice, with several accepted QOL instruments specific to lung cancer. We found good internal consistency scores for the FACT-L, FACT TOI, and the LCSS among newly diagnosed lung cancer patients who smoke. Furthermore, both the FACT-L and FACT-L TOI demonstrated a strong correlation with the LCSS, suggesting good convergence validity. Either of these instruments are appropriate measures for QOL in lung cancer patients. Establishing that these instruments have high convergence validity allows the researcher to focus only upon the most appropriate QOL tool for the research aims. Given the conceptual difference between the two instruments, it is important to carefully consider the research aims when selecting the appropriate QOL measurement instrument. Future studies should focus upon detecting change in QOL among smokers over time and compare changes in QOL after smokers quit.

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Figure 1.
Scatter plot exemplifying the relation between the LCSS and the FACT-L scales

Table 1

Sample characteristics (n=51)

Variables	Mean (SD)	Range	n	%
Age	56.7 (10.2)	25–80	51	
Gender				
Male			25	49.0
Female			26	51.0
Insurance				
Private			20	39.2
Medicare			3	5.9
Medicaid			14	27.5
Self-Pay			3	5.9
Private + Medicare			4	7.8
Medicaid + Medicare			7	13.7
Education				
Some HS			11	21.6
HS			13	25.5
GED			6	11.8
Some College			17	33.3
College/Graduate School			4	7.8
Race				
African American			7	13.7
White			43	84.3
Other			1	2.0
Marital status				
Married/Living With Partner			31	60.8
Widowed			4	7.8
Divorced			11	21.6
Never Married			5	9.8
Income				
<\$25K			21	42.9
\$25K–\$50K			10	20.4
>\$50K			9	18.4
Refused			5	10.2
Don't Know			4	8.2
Pathology				
Small Cell			11	21.6
Non-Small Cell			40	78.4
Stage				
Early (I–IIIA, limited)			16	32.0
Late (IIIB, IV, extensive)			34	68.0
Treatment prior to baseline				
No treatment			30	58.8
Surgery			6	11.8
Radiation (XRT)			6	11.8
Chemotherapy			4	7.8
Chemotherapy + XRT			5	9.8
CPD	16.0 (11.0)	0–40	51	
Years smoked	36.8 (11.2)	8–65	51	
Quit attempts	5.1 (14.5)	0–100	50	
FTND	5.0 (1.9)	1–9	46	

Table 2

Number, mean score, standard deviation and ranges for the FACT-L and LCSS

Scale	n	Mean	SD	Range
FACT-L *				
PWB	51	16.5	7.3	1–27
SWB	51	20.4	5.6	4–28
FWB	51	13.8	5.9	2–27
EWB	51	14.2	4.8	3–24
LCS	51	16.2	5.2	5–28
FACT-L	51	81.1	20.1	34–123
FACT TOI	51	46.3	15.7	14–76
LCSS **				
Appetite	50	38.9	29.1	0–86
Fatigue	50	55.4	24.0	0–100
Coughing	50	42.6	28.7	0–100
Dyspnea	50	43.3	32.0	0–100
Hemoptysis	50	11.0	21.5	0–75
Pain	50	39.0	32.2	0–100
Symptoms	50	37.7	30.5	0–100
ADL	50	49.2	29.6	0–98
QOL	50	42.9	28.3	0–100
Total score	50	40.0	19.1	9.9–86.3

* A higher score corresponds with a higher (better) QOL

** A lower score corresponds with a higher (better) QOL

Table 3

Mean score (SD) of FACT TOI, FACT-L and LCSS by treatment* and lung cancer stage*

Instrument	Treatment Naive		Prior Treatment	
	n	Mean (SD)	n	Mean (SD)
FACT TOI	30	47.5 (16.14)	16	45.6 (15.59)
FACT-L	30	81.9 (19.39)	16	81.1 (21.91)
LCSS	30	38.0 (2.39)	15	43.1 (18.12)
Instrument	Early Stage**		Late Stage***	
	n	Mean (SD)	n	Mean (SD)
FACT TOI	16	48.8 (18.01)	34	44.4 (14.23)
FACT-L	16	84.1 (22.80)	34	79.1 (18.79)
LCSS	16	35.7 (18.20)	33	43.1 (18.79)

* No statistically significant differences detected

** Stage IA–IIIA non-small cell, limited stage small cell

*** Stage IIIB–IV non-small cell, extensive stage small cell

Table 4

Internal consistency of the FACT-L and the LCSS

Scale	Number of items	n	Cronbach's alpha
PWB	7	49	0.89
SWB *	7	35	0.81
EWB	6	51	0.83
FWB	7	51	0.83
LCS	7	50	0.61
Total FACT-L *	34	34	0.87
FACT-L TOI	21	49	0.88
Total LCSS	9	50	0.84

* Data presented only for those who completed all items

Table 5

Reported LCSS mean score (SD) from the Garces et al. (20) sample

LCSS	Mean (SD)
Appetite	26.1 (5.57)
Fatigue	44.4 (6.24)
Coughing	34.5 (5.66)
Dyspnea	37.0 (5.96)
Hemoptysis	5.2 (1.27)
Pain	16.2 (2.53)
Symptoms	19.1 (5.34)
ADL	26.6 (7.84)
QOL	31.1 (8.03)
Total score	28.7 (5.09)

 $r = -0.76$