Reproducibility of the Brazilian Portuguese version of the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire used in conjunction with its lung cancer-specific module*

Reprodutibilidade da versão em português do Brasil do *European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire* em conjunto com seu módulo específico para câncer de pulmão

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Abstract

Objective: The assessment of the quality of life in patients with lung cancer has become one of the main goals in current clinical trials. To assess the quality of life of these patients, the most widely used instrument is the 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30) in conjunction with its supplemental 13-item lung cancer-specific module (QLQ-LC13). The objective of this study was to assess the reproducibility of the Brazilian Portuguese version of these questionnaires. **Methods:** A prospective study involving 30 stable outpatients with lung cancer who completed the instruments on the first day of the study and two weeks later. **Results:** The test-retest reproducibility using the intraclass correlation coefficient for the EORTC QLQ-C30 and the QLQ-LC13 ranged from 0.64 to 1.00 and from 0.64 to 0.95, respectively. No correlations were found between the domains of the instruments and clinical parameters. **Conclusions:** Our findings show that these instruments were reproducible in this sample of patients with lung cancer in Brazil.

Keywords: Lung neoplasms; Reproducibility of results; Quality of life.

Resumo

Objetivo: A avaliação da qualidade de vida em pacientes com câncer de pulmão tem se tornado um dos principais objetivos em ensaios clínicos atuais. Para avaliar a qualidade de vida desses pacientes, o instrumento mais utilizado é o *36-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire* (EORTC QLQ-C30) em conjunto com seu módulo específico para câncer de pulmão com 13 itens (QLQ-LC13). O objetivo deste estudo foi avaliar a reprodutibilidade da versão em português do Brasil desses questionários. **Métodos:** Estudo prospectivo com 30 pacientes ambulatoriais estáveis com câncer de pulmão, os quais completaram os instrumentos no primeiro dia do estudo e duas semanas depois. **Resultados:** A reprodutibilidade teste-reteste através do coeficiente de correlação intraclasse para o EORTC QLQ-C30 e o QLQ-LC13 variou de 0,64 a 1,00 e de 0,64 a 0,95, respectivamente. Não houve correlações entre os domínios dos instrumentos e os parâmetros clínicos. **Conclusões:** Estes achados demonstram a reprodutibilidade dos instrumentos utilizados nesta amostra de pacientes com câncer de pulmão no Brasil.

Descritores: Câncer de pulmão; Reprodutibilidade dos testes; Qualidade de vida.

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Introduction

Worldwide, lung cancer is one of the most common types of neoplasia, and, despite recent advances, its prognosis remains poor, with an overall five-year survival rate of less than 15%.[1] In Brazil, the number of new cases of lung cancer estimated for 2010 is 17,800 among men and 9,930 among women. These values correspond to an estimated incidence of 18 new cases per 100,000 men and 10 new cases per 100,000 women.[2]

In the past, studies of patients with lung cancer focused on traditional outcomes, such as survival, disease-free intervals, or local control. However, due to the high morbidity and mortality of this disease, the inclusion of instruments to assess quality of life as an outcome measure has become extremely important.[3]

The Karnofsky scale[4] and the Eastern Cooperative Oncology Group (ECOG) scale,[5] which are widely used for assessing the physical performance of patients, are based only on observation by health professionals and do not take into account the views of the patients themselves. In contrast, the assessment of quality of life using generic or specific questionnaires provides information not only about physical issues but also about psychosocial, functional, and spiritual aspects, and more importantly, from the perspective of the patient. The 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ-C30)—in conjunction with its supplemental 13-item lung cancer-specific module (QLQ-LC13)—was specifically designed to assess the quality of life of patients with lung cancer and, worldwide, it is the most widely used instrument in clinical trials. This questionnaire has appropriate psychometric properties, and its reproducibility and validity have been demonstrated in various languages and cultures. In addition, the score on the global scale (EORTC QLQ-C30) is considered to be a predictor of survival in patients with lung cancer.[6] Although this questionnaire is used in international multicenter studies involving facilities in Brazil, there have been no studies assessing the reproducibility of the Brazilian Portuguese-language version of this instrument. The use of reproducible questionnaires is essential, since it increases their internal validity in individual studies.[7] Therefore, the objective of this study was to assess the reproducibility of the Brazilian Portuguese-language version of the EORTC QLQ-C30 in conjunction with the QLQ-LC13 in a sample of patients with lung cancer.

Methods

This was a prospective observational study involving 30 patients diagnosed with lung cancer and under treatment at the Oncology/Pulmonology Outpatient Clinic of the Federal University of São Paulo/Paulista School of Medicine, in the city of São Paulo, Brazil. The inclusion criteria were as follows: a definite cytological or histological diagnosis of lung cancer; clinical stability (no changes in the symptoms of cough, expectoration, or dyspnea—these to have been registered on a structured form for outpatient follow-up, together with an affirmation that there had been no hospitalizations or changes in the treatment regimen in the 10 days preceding the interview); and a score equal to or greater than 21 on the Mini-Mental State Examination (MMSE).[8] The study was approved by the local research ethics committee, and all participants gave written informed consent.

In the first visit, the patients underwent clinical evaluation, using a structured form especially designed for patients with lung cancer, and completed the MMSE (Figure 1). The following independent variables were assessed: gender; age; smoking history and tobacco intake; histological type (adenocarcinoma, squamous cell carcinoma, small cell carcinoma, or other);[9] staging (in accordance with the 1997 tumor-node-metastasis classification, based on which patients with non-small cell lung cancer were classified as having stage IA, IB, IIA, IIB, IIIA, IIIB, or IV disease);[10] Karnofsky scale score;[4] spirometry results (FEV_1 and FVC in percentage of predicted, as well as the FEV_1/FVC ratio in percentage;[11] MMSE score; and EORTC QLQ-C30 and QLQ-LC13 scores.[12]

In both visits, the Karnofsky scale was administered before the questionnaires.[4]

Spirometry was performed at the end of the first interview, in accordance with the Brazilian Thoracic Association guidelines.[11]

The test-retest reproducibility of the EORTC QLQ-C30+QLQ-LC13 was determined after the questionnaire was administered twice, 15 days

apart, by the same researcher (Figure 1). In addition, the mean scores obtained on the various scales of the questionnaire were compared with the reference values established by the research group on quality of life of the EORTC, based on the minimum clinically significant difference, which, for this instrument, ranges from 5 to 10 points,[13,14] and comparisons with other reproducibility studies of other language versions of this instrument were performed.[1,15-20]

The protocol used the Brazilian Portuguese-language version of the EORTC QLQ-C30+QLQ-LC13 provided by the research group on quality of life of the EORTC, responsible for the development of the questionnaire, and followed the methods used for assessing reproducibility and for cross-cultural adaptation of other instruments in Brazil.[7,21-23]

The general questionnaire (EORTC QLQ-C30) comprises 30 questions related to five functional scales (physical functioning, role functioning, emotional functioning, social functioning, and cognitive functioning), a global health and quality of life scale, three symptom scales (fatigue, pain, and nausea/vomiting), and six single items regarding additional symptoms (dyspnea, insomnia, appetite loss, constipation, diarrhea, and financial difficulties). The QLQ-LC13, which is supplemental to the EORTC QLQ-C30, is a lung cancer-specific module comprising 13 questions related to a symptom scale (dyspnea) and nine single items regarding symptoms and adverse effects of treatment (cough, hemoptysis, mucositis, dysphagia, peripheral neuropathy, alopecia, chest pain, arm/shoulder pain, and pain elsewhere).[1,6] Points are scored according to the responses chosen by the patient. The options allowed by the questionnaire are "*não*" ("not at all"; one point), "*pouco*" ("a little"; two points), "*moderadamente*" ("quite a bit"; three points), or "*muito*" ("very much"; four points). In the two questions related to the global health and quality of life scale, the options to choose from range from "*péssima*" ("very poor"; one point) to "*ótima*" ("excellent"; seven points). The maximum total score on the questionnaire is 100. Regarding the functional scales and the global health and quality of life scale, higher scores are related to a better quality of life; however, for the symptom scales, higher scores correspond to a greater degree of the given symptom and, consequently, to a worse quality of life.[12]

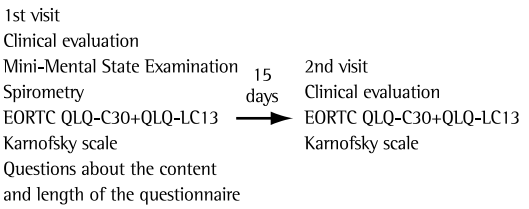

Figure 1 - Schematic diagram of the assessment protocol used in the two visits. EORTC QLQ-C30+QLQ-LC13: 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire + 13-item Quality of Life Questionnaire Lung Cancer.

The patients completed the questionnaire by reading the questions along with the researcher, as recommended in the accompanying manual. The environment was quiet, and interruptions were not allowed during the administration of

Table 1 - Characteristics of the 30 study participants.

Variable[a]	Result
Age, years	62.0 ± 10.4
Male gender, n (%)	23 (73.7)
Smoking history, n (%)	
Former smoker	27 (90)
Nonsmoker	3 (10)
Smoking history, pack-years	52.5 ± 33.4
Spirometry results	
FEV_1, % of predicted	75.0 ± 19.1
FVC, % do predicted	86.7 ± 13.1
FEV_1/FVC, %	71.8 ± 12.2
Histological type, n (%)	
Adenocarcinoma	14 (46.7)
SCC	9 (30)
SCLC	2 (6.7)
Other	5 (16.7)
Karnofsky scale	93.2 ± 9.9
Staging, n (%)	
I or II	14 (46.7)
III	13 (43.3)
IV	3 (10)
MMSE	27.9 ± 1.9
Level of education, n (%)	
4 years of schooling	9 (30)
8 years of schooling	9 (30)
11 years of schooling	10 (33)
15 or more years of schooling	2 (6.7)

SCC: squamous cell carcinoma; SCLC: small cell lung cancer; and MMSE: Mini-Mental State Examination. [a]Values expressed as mean ± SD, except where otherwise indicated.

the questionnaire. The time required to complete the questionnaire was recorded for both visits.

For the purposes of the statistical analysis, the variables are expressed as means and standard deviations. The intraclass correlation coefficient (ICC) was calculated to assess the reproducibility of the questionnaire, whereas the kappa reliability coefficient was calculated to assess the reproducibility of each question. To compare two groups, we used the chi-square test for categorical variables, the Student's t-test for parametric continuous variables, and the Mann-Whitney test for nonparametric continuous variables. We used ANOVA, followed by the Bonferroni test for multiple comparisons, to compare three or more different subsamples of patients, separated by categorical variables, with the purpose of determining whether the subsamples showed similar distribution. Spearman's correlation coefficient was used for testing correlations between the spirometric variables and the questionnaire scores. Statistical analyses were performed with the aid of the Statistical Package for the Social Sciences, version 13.0 (SPSS Inc., Chicago, IL, USA). All hypothesis tests were two-tailed, and the level of significance was set at 5%.

Results

The principal characteristics of the 30 patients who completed the study are shown in Table 1. Of the patients studied, 63.3% were over 60 years of age.

There were no statistically significant differences between the genders in terms of age, Karnofsky scale score, spirometry results, MMSE score, staging, or histological type.

Of the three patients who had never smoked, only one had a history of passive smoking. Smoking predominated in the male gender ($p = 0.04$). There was a statistically significant difference between the genders in terms of mean smoking history, which was greater in men than in women (53.2 ± 31.6 vs. 29.6 ± 25.5 pack-years; $p = 0.02$).

Of the study participants, 8 (26.7%) were diagnosed with COPD, in accordance with the Global Initiative for Chronic Obstructive Lung Disease guidelines.[24]

All patients met the stability criteria, there being no significant clinical changes, according to the medical evaluation. The drug treatment regimen used by the patients remained unaltered during the 15-day interval between the two administrations of the questionnaires.

The mean scores on each scale of the EORTC QLQ-C30+QLQ-LC13 in the two visits are shown in Table 2.

Excellent intraobserver reproducibility was found for all EORTC QLQ-C30+QLQ-LC13 scores (Table 2). All ICCs presented $p < 0.01$.

Kappa reliability coefficients and p values were calculated individually for each question

Table 2 - Mean scores on the scales and single items of the 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire, in conjunction with the 13-item Quality of Life Questionnaire Lung Cancer, obtained in the two visits (15 days apart), as well as the respective intraclass correlation coefficients.

Scale or item	Visit 1	Visit 2	ICC
EORTC QLQ-C30			
Global health and quality of life	70.1	68.3	0.91
Physical functioning	74.1	13.8	0.92
Role functioning	75.6	81.7	0.83
Emotional functioning	71.7	76.1	0.80
Cognitive functioning	76.1	81.1	0.88
Social functioning	86.1	90.0	0.84
Fatigue	19.6	25.2	0.91
Nausea and vomiting	5.0	6.1	0.79
Pain	20.0	22.8	0.82
Dyspnea	31.1	30.0	0.80
Insomnia	25.6	16.7	0.68
Appetite loss	12.2	14.4	0.81
Constipation	13.3	17.8	0.64
Diarrhea	4.0	4.0	1.00
Financial difficulties	22.2	25.6	0.77
QLQ-LC13			
Dyspnea	27.8	27.0	0.95
Cough	42.2	53.3	0.82
Hemoptysis	5.6	5.6	0.85
Mucositis	7.8	4.4	0.81
Dysphagia	11.1	11.1	0.79
Peripheral neuropathy	15.6	18.9	0.84
Alopecia	11.1	5.6	0.65
Chest pain	17.8	15.6	0.95
Arm/shoulder pain	21.1	18.9	0.95
Pain elsewhere	21.1	26.7	0.82

ICC: intraclass correlation coefficient; EORTC QLQ-C30: 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire; and QLQ-LC13: 13-item Quality of Life Questionnaire Lung Cancer.

Table 3 - Mean scores on the scales of the 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire reported in several reproducibility and cross-cultural adaptation studies involving patients with lung cancer.

Study	GHQoL	PF	RF	EF	CF	SF	FA	NV	Pain	DY
Present study	70.1	74.1	75.6	71.7	76.1	86.1	19.6	5.0	20.0	31.1
Scott et al.[14]a	56.6	71.9	61.5	68.9	82.3	71.3	41.1	10.8	29.7	37.9
Wan et al.[20]	56.3	72.3	52.7	64.9	68.3	50.7	40.9	21.3	39.7	31.0
Nickalsson & Bergman[1]	50.1	52.9	46.6	72.6	77.2	65.2	52.6	14.4	34.2	46.4
Guzelant et al.[17]	56.9	55.5	74.0	74.9	80.2	70.1	46.8	17.0	37.8	30.2
Nowak et al.[25]	55.0	90.0	57.0	76.0	84.0	67.0	42.0	7.0	38.0	39.0
Chie et al.[16]	63.2	72.2	74.7	75.0	78.8	76.7	34.3	5.6	19.4	24.1
Schwarz & Hinz[19]	70.8	90.1	88.0	78.7	91.2	91.0	17.1	2.8	15.4	8.1
Apolone et al.[15]	70.2	78.1	83.1	76.1	80.3	91.1	22.0	3.4	18.5	-
Kobayashi et al.[18]	56.7	65.8	57.3	70.0	83.6	77.3	39.4	6.7	29.3	41.0

GHQoL: global health and quality of life; PF: physical functioning; RF: role functioning; EF: emotional functioning; CF: cognitive functioning; SF: social functioning; FA: fatigue; NV: nausea and vomiting; and DY: dyspnea. [a]Reference values.

on the EORTC QLQ-C30+QLQ-LC13 in the first visit and compared with those calculated in the second visit, with the purpose of determining the reproducibility of the questions after 15 days of clinical stability. The kappa reliability coefficients were lower than 0.4 for questions 12, 16, 18, 22, 26, 27, and 43b. It was not possible to calculate the coefficients for questions 5, 13, 14, 15, 17, 19, 20, 21, 23, 30, 32, 36, 37, or 38. The remaining questions showed a moderate to good level of concordance.

Spearman's correlation coefficient revealed no correlation between spirometric variables and the scores on the scales of the questionnaire studied.

In the present study, the mean scores on the global health and quality of life scale and on the social functioning scale of the EORTC QLQ-C30 were above the reference values; regarding the symptom scales, the mean scores on the fatigue scale were below the reference values, whereas, on the pain and nausea/vomiting scales, they were similar to the reference values.[14] The mean scores on all scales of the QLQ-LC13 were similar to the reference values.[14] Table 3 shows the reference values and the mean scores reported for the EORTC QLQ-C30+QLQ-LC13 scales in several reproducibility and cross-cultural adaptation studies involving patients with lung cancer.

In both visits, we registered the time required for each patient to complete the questionnaire. For the time required to complete the questionnaire, the means, medians, standard deviations, and ranges are shown in Table 4. There was a statistically significant difference, as determined by the Student's t-test, between the first and second visits in terms of the times required to complete the three instruments used.

The patients responded to a number of questions about the difficulties in completing the EORTC QLQ-C30+QLQ-LC13. Regarding length, 94% found it appropriate, 2% found it short, and 8% found it long. Regarding difficulty, 92% stated that the instrument was easy to understand and 8% were of the opinion that some questions were confusing. Regarding the terms used in the questionnaire, 92% of the patients did not know the meaning of the word "*obstipado*" ("constipated"; question 16), which was explained as having "*intestino preso*" ("intestinal obstruction"). Another term that caused difficulties, in 16% of the sample, was

Table 4 - Time (in min) required to complete the 30-item European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire in conjunction with the 13-item Quality of Life Questionnaire Lung Cancer at the two time points (first and second visits).

Time point	Mean	Median	SD	Range	p*
First visit	9.0	8.0	3.2	5-18	< 0.001
Second visit	8.3	7.5	4.1	3-24	

*Student's t-test.

found in question 10: "*Você precisou repousar?*" (Did you need to rest?) "*Repousar*" (literally, "repose"), which is the more formal term in Portuguese, was explained as "*descansar*" ("rest"). In the QLQ-LC13, question 33, "*Sentiu falta de ar enquanto repousava*?" (Were you short of breath while resting?), caused difficulties in 12% of the sample. "*Repousava*" (literally, "reposed") was explained as "*descansava*" ("rested").

Discussion

The objective of this study was to assess, in a population of patients in Brazil, the reproducibility of the Brazilian Portuguese-language version of the EORTC QLQ-C30+QLQ-LC13. The questionnaire showed excellent reproducibility when administered at two time points, 15 days apart, to a population of patients with lung cancer.

The EORTC QLQ-C30+QLQ-LC13 is a widely used instrument to assess the quality of life of patients with lung cancer and has undergone cross-cultural validation for use in many countries.[1,15-20,25] In general, the patients in the present study had functional and symptom scale scores that were similar to the reference values established by the EORTC quality of life research group. However, the analysis of the findings of studies of this questionnaire conducted in other countries shows that there is great variability.[1,15-20,25] Many factors can contribute to this variability. One is the existence of significant cultural differences between countries, differences that influence the conceptualization of and the reaction to various measurement instruments. There are substantial differences between countries in terms of scores on many scales, especially those related to symptom perception.[17,19]

Reproducibility was assessed by the test-retest method. The reproducibility values for the EORTC QLQ-C30+QLQ-LC13 found in the present study ranged from 0.64 to 1.00 and are very similar to the values reported in previous validation studies of other language versions of this instrument. The variation in ICC was 0.46-0.85 for the Taiwan Chinese version,[25] 0.32-0.80 for the Chinese version,[20] 0.58-0.90 for the Italian version,[15] 0.70-0.94 for the Turkey version,[17] and 0.63-0.90 for the Japanese version.[18]

The ICC values for most scales of the EORTC QLQ-C30+QLQ-LC13 were higher than 0.75, except for the insomnia, constipation, and alopecia scales. One possible reason for lower correlations on these scales is the fact that, in our sample, there was a predominance of elderly individuals (63.3% were over 60 years of age), in whom these symptoms are more unstable and more likely to change; our findings are in agreement with those reported in the validation study of the Chinese version of the EORTC QLQ-C30+QLQ-LC13.[20] In other words, low ICCs are related to scales measuring symptoms that are vulnerable to changes in perception over short periods of time.

Therefore, we can state that the Brazilian Portuguese-language version of the EORTC QLQ-C30+QLQ-LC13 showed good reproducibility in this sample of patients. Similarly, we found good reproducibility, as measured by the kappa coefficient, for most questions.

In the present study, the EORTC QLQ-C30+QLQ-LC13 did not correlate with disease stage, although some studies have demonstrated such an association.[1,26] This might be due to the inhomogeneous distribution of our sample, in which most patients had early-stage disease (46.7% had stage I or II disease) and were under post-treatment follow-up (76.7%), at which point symptoms are much less common. It is known that the prevalence of uncontrolled symptoms, especially fatigue, dyspnea, pain, and anorexia, is higher in patients with progressive disease.[26]

Regarding pulmonary function, patients with reduced FEV_1 are generally expected to have worse functional scores and more symptoms, especially dyspnea.[1] However, studies of cancer patients, such as those assessing the quality of life of long-term, non-small cell lung cancer survivors,[27,28] have reported no correlations between altered pulmonary function and quality of life.

In the present study, the mean FEV_1 was 75% of predicted, and, as in the studies mentioned above, the pulmonary function test parameters (FVC, FEV_1, FEV_1/FVC) did not correlate with the quality of life scores. This might be related to the limited ability of physiological tests to explain the variability in individual symptom perception.[29] In addition, there was a very small number of patients with FEV_1 below 50%

of predicted in our sample, which might have contributed to the lack of correlation between this variable and the quality of life scores.

One study demonstrated that quality of life is negatively but not significantly affected by smoking. According to the same study, the quality of life of individuals who continue to smoke after diagnosis tends to be worse, whereas there is a decrease in morbidity and mortality among those who quit smoking after diagnosis.[30] In our study, none of the patients continued to smoke after the diagnosis was established. Therefore, it was not possible to evaluate the impact of continued smoking on the quality of life of the patients.

In the present study, the patients required, on average, less than ten minutes to complete the EORTC QLQ-C30 and QLQ-LC13 together. This was due to the simplicity of the questions and response options, as well as to the fact that the patients considered this instrument easy to understand. Response time was shorter in the second visit than in the first. This might be related to the learning effect (the patients became familiar with the EORTC QLQ-C30+QLQ-LC13 through their participation). For most of the interviewees, that was their first contact with this type of instrument. Given that, in general, quality of life is assessed continuously, familiarization decreases the time spent and, consequently, the workload for health care teams and patients alike.

In this study, the reproducibility of the EORTC QLQ-C30+QLQ-LC13 was assessed in a convenience sample, whose size was similar to that of samples in validation studies of Brazilian Portuguese-language versions of other instruments.[7,21-23]

No change was made to the Brazilian Portuguese-language version sent us by the developers of the original instrument. However, one difficulty encountered is this study was related to some specific aspects of the translation of the questionnaire. The word "*obstipado*" ("constipated") was unknown to most patients. Therefore, we suggest to the developers of the questionnaire that "*obstipado*" ("constipated") be replaced with "*intestino preso*" ("intestinal obstruction") in order to facilitate understanding and, consequently, the use of the instrument by patients in Brazil.

We conclude that the reproducibility of the Brazilian Portuguese-language version of the EORTC QLQ-C30+QLQ-LC13 is very similar to that of the original version. In addition, this Brazilian Portuguese-language version is easy for patients to use and understand, requiring just a few minutes for completion.

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