Original Article

Development of Improved Version of Quality of Life Assessment Instrument for Lung Cancer Patients Based on Traditional Chinese Medicine (QLASTCM-Lu)*

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ABSTRACT **Objective:** To develop an improved version of the Quality-of-Life Assessment instrument for Lung Cancer Patients Based on Traditional Chinese Medicine (QLASTCM-Lu) and to evaluate its psychometric property. **Methods:** The structured group method and the theory in developing rating scale were employed to revise the preliminary scale. The psychometric property (reliability, validity, and responsiveness) of the established QLASTCM-Lu (modified) were evaluated by quality of life data measured in 100 lung cancer patients. Statistical analyses were made accordingly by way of correlation analysis, factor analysis and paired *t*-test. **Results:** The internal consistency reliability of the overall scale and all domains was from 0.80 to 0.94. Correlation and factor analyses demonstrated that the scale was good in construct validity. The criterion validity was formed with European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire-Lung Cancer (EORTC QLQ-LC43) as the criterion. Statistically significant changes were found apart from such domain as "mental condition" and "social function", with the standardized response means being close to those of QLQ-LC43. **Conclusion:** QLASTCM-Lu (modified) could be used to measure the quality of life of lung cancer patients with good reliability, validity and a certain degree of responsiveness.

KEYWORDS lung cancer, quality of life, Chinese medicine, scale, European Organization for Research and Treatment of Cancer

Lung cancer is the leading cause of cancer-related death in both more and less economically developed countries.[1,2] Although treatment of lung cancer has been greatly improved, the prognosis is not optimistic.[3,4] The most common complaints of lung cancer patients are cough, sputum, blood in phlegm, low grade fever, chest pain and ect. How to improve quality of life (QOL) has become the focus of cancer research. The assessment on QOL of lung cancer patients is a multi-mode, subjective and dynamic process. And such assessment is achieved through the instrument. Currently, there are three major instrument systems in the field of cancers: Functional Assessment of Cancer Therapy (FACT) in the United States, European Organization for Research and Treatment of Cancer (EORTC) and Quality of Life Instruments for Cancer Patients-General module (QLICP-GM) in China.[5-8] However, these instruments are all developed based on the theory of Western medicine (WM). As Chinese medicine (CM) and WM are completely different two systems in the basis and method of understanding, they have absolutely varied views on health, disease diagnoses and treatment. For CM, cancers appear as a local response to the systemic disease, which should be dealt with primarily based on overall comprehensive treatment through regulating the body microenvironment and enhancing body resistance to control tumor growth.[9,10]

It advocates "living with tumors" and the improvement of QOL.[11] The treatment of CM is not equivalent to chemotherapy; therefore, when judging the efficacy by taking advantage of tumor efficacy standards in WM can not show the characteristics of CM in the cancer treatment. Due to the insufficient of existing clinical efficacy evaluation system, it is quite necessary to develop QOL scale that fully and accurately reflects the characteristic of CM.

In 2009, Longhua Hospital Affiliated to Shanghai University of Traditional Chinese Medicine undertook the project of "CM Theory Special Project" under the National Program on Key Basic Research Project (973 Program)—Basic Theoretical Study of Instrument Evaluation Based on Syndrome Differentiation and Treatment of Malignant Tumors. Supported by the program, we have developed the QOL scale for lung cancer patients based on CM, which can highlight the clinical efficacy of CM. During the clinical survey of this scale, we found some existing problems through user feedback, like unpleasant after reading, difficult to understand or ambiguous items. Therefore, it is in urgent need to adopt a standardized scale development procedure to optimize and improve this scale.

METHODS

General Information

A total of 100 cases (45 males) confirmed lung cancer were enrolled in the survey from October 2016 to July 2017 and finally 92 effective scales were collected. Those patients came from Longhua Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, Shanghai Chest Hospital Affiliated to Shanghai Jiaotong University Affiliated to Shanghai Ninth People's Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai Changzheng Hospital and Qingdao Center Hospital. The mean age was 61.2 ± 10.1 years with a range of 31–79 years. Among them, 6 patients had bachelor degree or above, 18 had 3-year college education, 32 had senior middle school education, and 36 had junior middle school education. There were 63 cases in-patients and 29 out-patients.

Item Revision and Instrument Formation

The instrument was revised by general and specific module. To begin with, a first modified version of Quality of Life Assessment Intrument for Lung Cancer Patients (QLASTCM-Lu) has been developed based on the preliminary revisions of items through quantitative survey and qualitative interview. Then the importance, relevance and feasibility of items pool (Table 1) were established by 130 lung cancer patients, 70 oncologists (CM doctors and WM doctors), 60 oncology nurses, 50 social scientists and 50 psychiatrists.

Table 1.   Brief Entry Description of QLASTCM-Lu (modified)

No.	Brief description of the entry	No.	Brief description of the entry	No.	Brief description of the entry
1	Have powerless feeling	18	Have bosom friends	35	With no appetite
2	Susceptible to illness	19	Satisfied with one's human relationship	36	Chest congestion
3	Have difficulty in walking long distances	20	Treatment hinders socializing	37	Insomnia
4	Have difficulty in walking short distances	21	Over-worried about the disease	38	Drowsiness
5	Tiredness aggravates discomfort	22	Forgetfulness	39	Easy to sweat
6	Skinny	23	Active thinking	40	Aerophobia
7	Bedridden	24	Satisfied with one's physical conditions	41	Dry mouth
8	Happiness	25	Satisfied with natural environment	42	Night sweats
9	In a light mood	26	Confident in treatment	43	Dizziness
10	Impatient	27	Satisfied with the climate	44	Aching lumbus and limp legs
11	Sadness	28	Feel chest pain	45	Nausea
12	Sighs and groans	29	Coughing	46	Constipation
13	Worried about the condition	30	Phlegm in the throat	47	Vomit
14	Satisfied with work performance	31	Hoarse voice	48	Healthy all week
15	Satisfied with living ability	32	Bloody sputum	49	Quality over a week
16	Satisfied with one's economic condition	33	Dyspnea		
17	Care available	34	Feel short of breath		

Assessment Methods

A formal survey was conducted among 100 lung cancer patients via a complete QLASTCM-Lu (modified) with 49 items , and scales have to be check and perfect on the spot. Each patient was asked to answer the scale at the time of admission to the hospital by themselves. To evaluate responsiveness of the scale, each patient received two longitudinal

measures (before starting therapy and two weeks later). In addition, European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire-Lung Cancer (EORTC QLQ-LC43) was used to compare QLASTCM-Lu (modified) as the criterion. Assessment contents of psychometric property contain reliability (internal consistency), validity (content validity, structural validity, criterion validity) and reactivity of instruments.

Scoring Methods

QLASTCM-Lu (modified) consists of 5 dimensions of "physical status", "mental condition", "social function", "unity of man and nature", and "symptoms" as well as another two items concerning overall health status, totaling 49 items. Each item is set with 5 grades specifically (not at all, a little, certain, quite and extremely often). Forward item is scored from 1 to 5 points in scoring, and the reverse entry is scored reversely, that is, 5 points for the 1st grade, 4 for the 2nd grade, and the like. Scores in each domain are obtained by adding the within-domain item scores, and the total score is obtained by adding scale scores. Apart from 13 items (T8, T9, T14, T15, T16, T17, T18, T19, T23, T24, T25, T26, T27) were directly scored, those items were scored in reverse. The scoring method adopted by EORTC QLQ-LC43 is similar to the aforementioned one.[12] The higher the standard scores are in the functional field and field of overall health status, the better the functional status and QOL; and the higher the standard score in the field of symptom, the more symptoms or problems there are.[13]

Statistical Analysis

All statistical tests were double-sided tests. When the value of P was no bigger than 0.05, differences tested will regarded as statistically significant. Analysis software used were SAS 9.4, AMOS 17.0 and R. Spass 17.0 statistcal software was used for statistical analysis. Adopting correlation analysis and factor analysis to explain the structure validity; and verify calibration validity with correlation analysis.

RESULTS

Reliability Analysis

The obtained data were used to respectively calculate the internal consistency coefficients in each field of the QLASTCM-Lu (modified) and EORTC QLQ-LC43 instrument α (Tables 2 and 3). Both the internal consistencies of the above 2 instruments were comparatively high (The Cronbach's αs were both larger than 0.8).

Table 2. Cronbach's α of QLASTCM-Lu (Modified) in All Fields

Field	Cronbach's alpha
Physical function	0.872261
Mental condition	0.806166
Social function	0.802611
Unity of man and nature	0.818202
Specific module	0.904924
Overall health status	0.940261

Table 3. Cronbach's α of QLQ-LC43 in All Fields

Field	Cronbach's alpha
Physical function	0.815631
Emotion recognition	0.853923
Role function	0.806828
Social function	0.803247
Symptoms	0.894663
Overall health status	0.941495

From the correlation analysis and taking the correlation coefficient of QLASTCM-Lu>0.4 as the standard, it can be shown that: (1) in the field of mental condition: the subjects in T8 "I feel happy", and the corresponding correlation coefficient was 0.3806, a rather low correlation; (2) in the field of social function: subjects in T20 "I think that social activities were interrupted by the current physical status or treatment process" with a correlation coefficient of 0.3396; those in T21 "I am so worried about the disease that I have lost control of myself" with a correlation coefficient of 0.3366; T22 "I am forgetful" with a correlation coefficient of 0.1875, a low correlation. (3) In the field of specific module: for subjects in T37 with "I suffer from insomnia ", the correlation coefficient was 0.3634; the correlation coefficient is low at 0.3803 for subjects in T42 "I perspire often during sleep". The content validity for other fields was rather good.

Structural Validity

Based on the correlation analysis, if factor analysis is made with data of 92 lung cancer patients and the characteristic root >1 as the standard, 12 common factors need to be extracted; when the cumulative variance contribution rate is greater than 50.00%, 5 common factors need to be extracted (with the cumulative variance contribution rate of 53.03%). According to the results of PA analysis, it

was recommended to choose 5 common factors. A confirmatory factor analysis of such 5 common factors was conducted, then experts opinions and the statistical analysis were combined, the following 4 items were removed: the subjects in T8 "I feel happy", T20 "I think that my social activities were interrupted by the current physical status or treatment process", T22 "I am forgetful", T42 " I often perspire during sleep". According to the confirmatory factor analysis of the remaining 45 items, each factor loading coefficient of all items was not 0, and no improper items were found in all fields.

Criterion Validity

Without a golden standard, EORTC QLQ-LC43 was used as criterion for evaluation. From the total score, it can be seen that there was a high correlation between such two instruments as QLASTCM-Lu (modified) and EORTC QLQ-LC43 ($r>0.8$), indicating that the lung cancer symptom instrument generally had high consistency with the criterion validity instrument. The correlation between these two instruments was high ($r>0.8$) with regard to overall assessment of all items, demonstrating a high consistency between "QOL" and "health status" therein. Considering the correlation coefficients of the scores in all fields of QLQ-LC43 and QLASTCM-Lu (modified), it showed that such two instruments had relatively high correlation in the same and similar fields. For example, the correlation coefficient between specific modules and symptom field was 0.86005, larger than that of other fields (Tables 4 and 5).

Responsiveness

The responsiveness of the QLASTCM-Lu (modified) was evaluated by paired t-test and the standardized response mean (SRM). It can be seen in the QLASTCM-Lu (modified) that significant statistical differences ($P<0.05$) exist in the scoring as physical status, mental condition and specific module.

Table 4.   Overall Assessment of Total Scores of QLASTCM-Lu (Modified) and QLQ-LC43

Index	r value
Total score of QLASTCM-Lu (modified) and QLQ-LC43	0.80877
Total score of QLASTCM-Lu (modified) and T48	−0.60023
Total score of QLASTCM-Lu (modified) and T49	−0.60794
Total score of QLASTCM-Lu (modified) and QLQ-LC43 T42	−0.56328
Total score of QLASTCM-Lu (modified) and QLQ-LC43 T43	−0.59148
QLASTCM-Lu T48 and QLQ-LC43 T42	0.84210
QLASTCM-Lu T48 and QLQ-LC43 T43	0.83403
QLASTCM-Lu T49 and QLQ-LC43 T42	0.81793
QLASTCM-Lu T49 and QLQ-LC43 T43	0.85963

Note: by Pearson-related analysis

Table 5.   Correlation Coefficients between QLASTCM-Lu and QLQ-LC43 in All Fields

Index	r value
Physical condition and body, emotion	0.67275
Mental condition and emotion, recognition	0.61138
Social function and role function, social function, economic difficulties	0.45892
Special module and fatigue, nausea and vomiting, pain, insomnia, loss of appetite, constipation, diarrhea, shortness of breath, cough, hemoptysis, oral ulcer, dysphagia, peripheral neuropathy, hair loss, chest pain, arm or shoulder pain, or in other pain sites	0.86005

Note: by Pearson-related analysis

The SRM of such fields as physical status, mental condition, specific module and the total scores was normally good (|SRM|>0.2), and that of other fields remained quite general (Table 6).

DISCUSSION

The development and assessment of a QOL instrument is a long process.[14] Just like what Schipper said, it had better modify the existing instruments than develop a new one. This paper uses multiple methods and indices in the modification and assessment of QLASTCM-Lu (modified). Reliability coefficient is utilized to measure the reliability level. Currently, there are many assessment methods of reliability, among

Table 6.   Responsiveness of QLASTCM-Lu (Modified) (n=92, Score, $\bar{x} \pm s$)

Domain	Baseline	After treatment	Change	T	P value	ES	SRM
Physical function	14.28 ± 5.02	13.56 ± 4.58	−0.72 ± 3.20	2.17	0.0330	0.14	0.23
Mental condition	13.74 ± 4.02	13.10 ± 3.88	−0.64 ± 2.60	2.34	0.0217	0.16	0.25
Social function	27.54 ± 6.08	26.92 ± 5.82	−0.62 ± 3.74	1.59	0.1145	0.10	0.17
Unity of man and nature	11.74 ± 3.46	11.34 ± 3.32	−0.40 ± 2.22	1.73	0.0878	0.12	0.18
Specific module	33.82 ± 9.10	32.06 ± 8.24	−1.76 ± 5.86	2.88	0.0050	0.19	0.30
Overall situation	101.14 ± 21.54	97.00 ± 20.36	−4.14 ± 12.84	3.09	0.0027	0.19	0.32

Notes: SRM: standardized response mean; ES:

which internal consistency reliability Cronbach's α is the main one. As for the judgment of reliability level, there is no fully accepted standard. Generally, the Cronbach's α should be at least 0.70.[15] The results of this research showed that the internal consistency reliability Cronbach's α was greater than 0.80, indicating that the reliability of the instrument is better.

The assessment on reliability is mainly made from 3 aspects, namely content validity, structural validity and criterion validity.[16] As shown by the analysis results based on quantitative measurement of content validity in this instrument, subjects in T8 "I feel happy", T20 "I think that my social activities are interrupted by current physical status or treatment process", T21 "I am so worried about disease that I have lost control of myself", T22 "I am forgetful" and T42 "I perspire often during sleep". The correlation coefficient in the aforementioned five items is respectively smaller than 0.4. Meanwhile, CM clinical oncology experts opinions are comprehensively taken into consideration. It's decided that T21 should be included into the field of mental condition and other 4 items as T8, T20, T22 and T42 should be deleted. Many patients describe items T8 "I feel happy" and T20 "I think that my social activities are interrupted by the current physical status or treatment process" as "the item isn't suitable for me to answer", while item T22 has quite little relation to social function field, and T42 wasn't specific symptoms of lung cancer patients. Therefore, it's determined such 4 items directly be deleted and other 45 items remained to be analyzed.

Structural validity is mostly assessed through correlation analysis and factor analysis.[17] The results in this paper demonstrate that the structure of the instrument basically matches the design concept, indicating its good structural validity. According to the confirmatory factor analysis of the remaining 45 items, each factor loading coefficient of all items is significantly not 0, and no improper items are found in all fields. In the next step, we could subdivide all fields and amplify sample quantity for further analysis based on the item response theory (IRT).[21]

Criterion validity refers to the correlation between instrument scores and certain exterior criterion, and it reflects the validity of testing behavior of individuals in a certain situation.[18] In this research, EORTC QLQ-LC43 was taken as the criterion. The research results indicated a high correlation between EORTC QLQ-LC43 and QLASTCM-Lu (modified); a relatively high correlation in the same and similar fields between such two instruments were seen while a rather low correlation existed between the "unity of man and nature" field and each field of EORTC QLQ-LC43. It demonstrates that the "unity of man and nature" field is quite particular with obvious Chinese characteristics and cultural features of CM.

As a vital feature for measurement tools (instruments), responsiveness refers to the ability of measurement tools to reflect longitudinal changes of certain tested properties over time, i.e. the ability of an instrument to detect the minor changes of certain tested properties.[19] As far as the measurement of QOL is concerned, responsiveness means the ability of an instrument to measure the changes of QOL over time. The assessment of internal responsiveness habitually adopts the method of paired t-test (or Wilcoxon signed-rank test etc.). However, considering the statistically significance of minor differences when the sample content is large, we have also calculated the effect index SRM. The results of this research suggest that the test results before and after treatment have changed.

It can be seen in the QLASTCM-Lu (modified) that significant statistical differences ($P<0.05$) exist in the scoring before and after in such fields as physical status, mental condition and specific module while that in fields of "unity of man and nature" and "social function" don't witness changes, which may arise from the fact that no obvious changes may occur due to wide ranges covered by such two fields. Generally, when the absolute value of SRM is around 0.2, it means low responsiveness; a medium responsiveness is indicated when SRM falls around 0.5 and quite good responsiveness when it's no smaller than 0.8.[20] According to this research, the SRM of such fields as physical status, mental condition and specific module and the total scores is normally good (SRM>0.2), and that of other fields remains quite general. Given 92 samples and 45 items being adopted in this research, it's intended to further enlarge the sample quantity in the survey so as to improve the evaluation effect of SRM; meanwhile, no specific levels are divided below fields in the instrument, which has led to the offsetting of items or dimensions in inconsistent directions of changes. Next we would to do further research on this scale. In conclusion, the QLASTCM-Lu (modified)

boasts fairly terrific reliability, good validity and certain responsiveness with cultural characteristics of CM. Therefore, it may be applied to the assessment of the QOL of lung cancer patients.

Conflict of Interest

The authors declare that they have no conflict of interests.

Author Contributions

Wang TT and You J designed the research and coordinated data collection. Wang TT and Chu L collected data, did data analysis and wrote the original text. He LY made the data analysis. Zhang M, Wang SM, Zhao AG, Chu L, Zhang LY and You SF collected the data. You J participated in drafting and editing. All authors read and approved the final manuscript.

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